EXHIBIT

DISCOVERY REFERENCED IN NOTICE

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	MDL No. 2419 Dkt. No: 1:13-md-2419-RWZ
THIS DOCUMENT RELATES TO: Suits Naming the Premier Defendants	

THE PREMIER DEFENDANTS' FIRST INTERROGATORIES, REQUESTS FOR PRODUCTION OF DOCUMENTS, AND REQUESTS FOR ADMISSION PROPOUNDED TO GLENN CHIN.

Come the Defendants, Premier Orthopaedic and Sports Medicine Associates of Southern New Jersey, LLC, trading as Premier Orthopaedic Associates; Premier Orthopaedic Associates Surgical Center, LLC; Kimberly Yvette Smith, M.D., a/k/a Kimberly Yvette Smith-Martin, M.D.; Thomas Dwyer, M.D.; Richard C. DiVerniero, M.D.; and Richard Strauss, M.D. (collectively, "Premier Defendants") , pursuant to Rules 26, 33, and 34 of the Federal Rules of Civil Procedure and the Local Rules for the District of Massachusetts, and propound the following Interrogatories, Requests for Production of Documents, and Requests for Admission to Glenn Chin.

Each of the following Interrogatories shall be answered under oath, in writing, separately, to the fullest possible detail, and in accordance with the definitions and instructions set forth below. The answers shall be signed by the person making them, and a copy of the answers, together with objections, if any, shall be served within thirty (30) days after the service date of these interrogatories.

You are under a duty to seasonably supplement your response with respect to any Interrogatory directly addressed to the identity and location of persons having knowledge of discoverable matters. You are under a duty to amend a prior response if you obtain information on the basis of which you know that the response was incorrect when made, or that the response, though correctly made, is no longer true, and the circumstances are such that a failure to amend the response is, in substance, a knowing concealment.

DEFINITIONS

1. As used in this document, the terms "person(s)" and "individual(s)" mean any natural individual in any capacity whatsoever or any entity or organization, including divisions, departments, and other units therein, and shall include, but not be limited to, a public or private corporation, partnership, joint venture, voluntary or unincorporated association, organization, proprietorship, trust, estate, governmental agency, commission, bureau, or department.

2. As used in this document, the term "document" means any medium upon which intelligence or information can be recorded or retrieved, and includes without limitation, the original and each copy, regardless of origin and location, of any book, pamphlet, periodical, letter, memorandum (including any memorandum or report of a meeting or conversation), invoice, bill, order form, receipt, financial statement, accounting entry, diary, calendar, telex, telegram, cable, report, record, contract, agreement, study, handwritten note, draft, working paper, chart, paper, print, laboratory record, drawing or sketch, graph, index, lists, tape, photograph, microfilm, data sheet or data processing card, or any other written, recorded, transcribed, punched, taped, filmed, or graphic matter, however produced or reproduced, which is in your possession, custody, or control, or which was, but is no longer, in your possession, custody, or control.

3. As used in this document, the terms "identification," "identify," or "identity," when used in reference to a natural individual, require you to state his or her full name and residential and business address. Use of the term "document" in connection with the Interrogatories requires you to state the number of pages and the nature of the document, its title, its date, the name or names of its authors, and recipients, and its present location and custodian.

4. "You and "your" refers to Glenn Chin and each of his present and former agents, representatives, and employees, attorneys and accountants, and each person acting or purporting to act on his behalf.

5. "Communication" means any oral or written utterance, notification, or statement of any nature whatsoever, by and to whomsoever made, including, but not limited to, correspondence, conversation, dialogue, discussions, interviews, consultants, and any other understanding between or among two or more persons.

INSTRUCTIONS

1. With respect to each Interrogatory, in addition to answering the question, you are to identify all documents that support, refer to, or evidence the subject matter of each Interrogatory and your answer thereto.

   If any or all identified documents are no longer in your possession, custody, or control because of destruction, loss, or any other reason, then you must do the following with respect to each and every document:

   A. Describe the nature of the document;

   B. State the date of the document;

   C. Identify the persons who sent and received the original and the copy of the document;

   D. State in as much detail as possible the contents of the documents; and

   E. State the manner and date of disposition of the document.

   If you contend that you are entitled to withhold from production any or all documents identified herein on the basis of attorney-client privilege, the work-product doctrine, or any other ground, then do the following with respect to each and every document:

   A. Describe the nature of the document;

   B. State the date of the document;

   C. Identify the persons who sent and received the original and a copy of the document;

   D. State the subject matter of the document; and

   E. State the basis upon which you contend you are entitled to withhold the document from production.

2. All documents produced should be organized and labeled to correspond to the specific Request in response to which they are being made available or should be produced as they are kept in the usual course of business.

3. The terms "and," "or," and "and/or" should be construed either disjunctively or conjunctively so as to bring within the scope of these Interrogatories and Requests any information that might otherwise be construed as outside their scope.

4. The term "any" should be construed to include the word "all," and "all" should be construed to include "any."

5. The present tense should be construed to include the past tense, and the past tense should be construed to include the present tense.

6. The singular should be construed to include the plural, and the plural should be construed to include the singular.

7. The terms "he" and "his" should be construed to include the words "she" and "her" or "hers," respectively and vice versa.

8. "Relating to," when referring to a document shall mean mentioning, describing, connected to or with, or discussing the stated subject matter.

INTERROGATORIES

1. Describe in detail your role at NECC and Ameridose, including job title, job description, and a description of your daily duties and activities in 2011 and 2012.

ANSWER:

2. Describe in detail the steps NECC took to compound, process, stopper, seal, package, and ship methylprednisolone acetate ("MPA") in 2011 and 2012, including but not limited to:

   a) The names of the individuals performing each step;

   b) The job titles for the individuals performing each step;

   c) The specific cleanroom or location in NECC's facility where each step took place;

   d) The tools, equipment, or machinery used for each step;

   e) Any changes to NECC's methods or procedures for compounding MPA, or the location where compounding MPA took place, that occurred in 2011 or 2012.

ANSWER:

3. Identify the total amount of MPA that NECC, and separately Ameriose, produced in each quarter of 2010, 2011, and 2012.

ANSWER:

4. Identify the types of vials and closures NECC used for MPA lots numbered 05212012@68, 06292012@26, and 08102012@51 (collectively "Contaminated Lots"), including whether the vials and enclosures were prewashed or presterilized, and identify their manufacturer(s) and from whom they were purchased by NECC.

ANSWER:

5. Identify any and all complaints that NECC and Ameridose received related to the sterility or safety of their products, including but not limited to complaints by customers, current and former employees, and state and federal government agencies.

ANSWER:

6. Identify any customers of NECC and Ameridose who performed site visits prior to placing orders with either company.

ANSWER:

7. Describe any policies, procedures, or protocols relating to or regarding customer site visits to the NECC facility, including the areas you allowed customers to inspect.

ANSWER:

8. Identify any customers who took the following actions prior to placing orders with NECC or Ameridose:

   a. Verified whether NECC's quality processes demonstrated that NECC was a reputable and safe supplier of sterile injectable compounds;

   b. Determined if NECC was an accredited compounding pharmacy;

   c. At least once annually, unannounced, visited NECCs corporate offices and compounding facilities and conferred with NECC's corporate, pharmacy, and compounding staff;

   d. Determined whether NECC had any product liability lawsuits filed against it for preparations compounded;

   e. Determined whether there had ever been recalls of any of NECC's compounded preparations;

   f. Evaluated NECC's standard operating procedures and manuals;

   g. Evaluated NECC's pharmacist technician training;

   h. Evaluated NECC's policies and procedures for sterility testing;

   i. Evaluated examples of batch reports for product being considered for outsourcing;

   j. Evaluated examples of quality-control reports;

   k. Obtained and evaluated history of the results of all NECC accreditation or regulatory surveys conducted of NECC's sites, including copies of significant regulatory actions;

   l. Determined if NECC could provide documentation of the end-product testing processes used to determine that compounded sterile preparations are sterile and free of pyrogens and unintended particulate matter;

   m. Evaluated whether NECC could assure that each compounded sterile preparation was sterile and free of pyrogens and unintended particulate matter according to professional established and accepted quality monitoring data;

n. Determined whether NECC performed nonviable and viable particle testing in primary engineering controls (e.g., laminar flow workbench, biological safety cabinet) and room air according to USP chapter 797 standards;

o. Determined whether NECC performed routine surface microbiological and fungal environmental monitoring to minimize contamination;

p. Determined whether NECC had a policy that required validation of new or changed facilities, equipment, processes, or container types, for sterility and repeatability;

q. Determined whether NECC met ASHP, NIOSH and USP chapter 797 guidelines for the handling of hazardous agents;

r. Evaluated NECC's quality management program, specifically as it relates to facility cleaning and validation, staff training, and competency assessment;

s. Evaluated NECC's risk assessment program to ensure that medication errors are not introduced by new or increased outsourced compounding activities; or

t. Determined whether NECC had a history of disciplinary or punitive actions by any regulatory agency.

ANSWER:

9. Describe any information you, NECC, or Ameridose provided to each customer in response to the inquiries identified in the previous Interrogatory.

ANSWER:

10. Identify any and all complaints NECC or Ameridose received related to their compliance with state or federal laws and regulations, including but not limited to complaints by customers, current and former employees, and state and federal government agencies.

ANSWER:

11. Identify and describe any way in which NECC's cleanrooms were modified, altered, or expanded by NECC or Ameridose.

ANSWER:

12. Identify any policies, procedures, or guidelines in place at NECC in 2012 that encouraged employees to disclose mistakes in the compounding process, even if the mistakes necessitated destruction of product or halting production.

ANSWER:

13. Describe all disciplinary or enforcement action taken against NECC or Ameridose by any state or federal government agency.

ANSWER:

14. Describe in detail Lisa Conigliaro Cadden's role at NECC in 2011 and 2012.

ANSWER:

VERIFICATION

STATE OF NEW JERSEY)
)
County of _____)

I, _____, after being duly sworn, hereby make oath that the foregoing answers to Interrogatories are true to the best of my knowledge, information, and belief.

_____

Sworn and subscribed before me this _____ day of _____, 2015.

_____
Notary Public

My commission expires on: _____.

REQUESTS FOR PRODUCTION

1. Produce all correspondence between you and any of the Premier Defendants, their employees, agents, or representatives.

RESPONSE:

2. Produce all correspondence and documents referring or related to the Premier Defendants' purchase of MPA from NECC in 2011 or 2012.

RESPONSE:

3. Produce all documents produced by the government to you during any civil, criminal, or administrative proceedings related to NECC's contaminated MPA.

RESPONSE:

4. Produce all policies, procedures, guidelines, instructions and training documents referring or relating to the compounding of MPA at the NECC facility.

RESPONSE:

5. Produce all documents referring or relating to NECC or Ameridose sending sufficient samples, by size or volume, to comply with USP 71 to ARL or any other testing laboratory.

RESPONSE:

6. Produce all documents referring or relating to any sterility, potency, endotoxin, or fungal testing that you received from ARL or any other laboratory related to MPA compounded by NECC or Ameridose in 2011 and 2012.

RESPONSE:

7. Produce all correspondence and documents referring or relating to fungal blooms or growth in or near NECC's cleanrooms.

RESPONSE:

8. Produce all documents referring or relating to any complaints that NECC or Ameridose received related to the sterility or safety of their products, including but not limited to complaints by customers, current or former employees, or state or federal government agencies.

RESPONSE:

9. Produce all documents referring or relating to any complaints NECC or Ameridose received related to their compliance with state or federal laws or regulations, including but not limited to complaints by customers, current or former employees, or state or federal government agencies.

RESPONSE:

10. Produce all correspondence and documents referring or relating to NECC's response to the meningitis outbreak, including but not limited to, steps NECC took to prepare for any inspections of its facility.

RESPONSE:

11. Produce all training and instructional material for sales staff at NECC or MSM.

RESPONSE:

12. Produce copies of any and all New Jersey Pharmacy Licenses issued to NECC and/or Glenn Chin, and all documents or communications between NECC and/or Glenn Chin and the New Jersey Board of Pharmacy, including those referring or related to the procurement or renewal of said Licenses.

RESPONSE:

REQUESTS FOR ADMISION

1. Admit that you compounded the MPA lots numbered 05212012@68, 06292012@26, and 08102012@51 (collectively "Contaminated Lots").

ANSWER:

2. Admit that you supervised the compounding of MPA lots numbered 05212012@68, 06292012@26, and 08102012@51 (collectively "Contaminated Lots").

ANSWER:

3. Admit that as a supervising pharmacist, you owed a duty to the Plaintiffs to ensure that NECC's cleanroom was sterile prior to compounding any medications, including MPA in 2012.

ANSWER:

4. Admit that as a supervising pharmacist, you owed a duty to the Plaintiffs to ensure that the MPA you compounded was sterile before you distributed it to customers.

ANSWER:

5. Admit that, had any of the Premier Defendants asked for a copy of NECC's license in 2011, you would have provided a valid and up-to-date Massachusetts pharmacy license.

ANSWER:

6. Admit that NECC represented to its customers, including the Premier Defendants, that it met or exceeded USP 797 standards.

ANSWER:

7. Admit that NECC represented to its customers, including the Premier Defendants, that its products, including MPA, were safe and sterile.

ANSWER:

8. Admit that the Massachusetts Board of Pharmacy ("Mass. BoP") inspected NECC on or about May 24, 2011.

ANSWER:

9. Admit that as a result of its inspection on or about May 24, 2011, the Mass. BoP issued an inspection report documenting its findings.

ANSWER:

10. Admit that NECC failed to submit a copy of the Mass. BoP's May 24, 2011 inspection report to the New Jersey Board of Pharmacy.

ANSWER:

11. Admit that the documents attached as Exhibit B are NECC's Logged Formula Worksheets for the Contaminated Lots.

ANSWER:

12. Admit that in each Logged Formula Worksheet in Exhibit B, the pharmacist referred to as "GC" is Glenn Chin.

ANSWER:

13. Admit that the Logged Formula Worksheet for lot 06292012@26, attached as Exhibit B, states that the MPA was autoclaved for twenty (20) minutes at 121 C. and 15 PSI.

ANSWER:

14. Admit that NECC's Standard Operating Procedures required that the MPA be autoclaved for fifteen (15) minutes at 121 C. and 15 PSI.

ANSWER:

15. Admit that the Logged Formula Worksheets in Exhibit B state that Joseph P. Connolly was the technician for MPA lots 05212012@68 and 06292012@26.

ANSWER:

16. Admit that Exhibit C is NECC's General Overview of Policies and Procedures for Compounding Sterile Products.

ANSWER:

17. Admit that Exhibit C states, in part:

C. Personnel

a. All sterile compounding is performed by properly trained and validated pharmacists (*no* technicians).

ANSWER:

18. Admit that NECC violated its own standard operating procedures by permitting Joseph Connolly (a technician) to compound two of the three contaminated lots.

ANSWER:

19. Admit that you owed a duty to NECC's customers to ensure that NECC's MPA was sterile prior to distributing it.

ANSWER:

20. Admit that NECC distributed some of the MPA from the Contaminated Lots prior to receiving final sterility, fungal, endotoxin, or potency testing results from its outside laboratory.

ANSWER:

21. Admit that the documents attached as Exhibit D are reports from Analytical Research Laboratories ("ARL") related to the sterility and endotoxin testing ARL performed on NECC's MPA from the Contaminated Lots.

ANSWER:

22. Admit that NECC submitted only two 5 mL vials of MPA from each of the Contaminated Lots to ARL for testing.

ANSWER:

23. Admit that USP standards for sterility testing required a larger sample size than two 5 mL vials per lot of MPA.

ANSWER:

24. Admit that USP 797 requires an ISO 5 space for stoppering vials of MPA.

ANSWER:

25. Admit that NECC stoppered the Contaminated Lots in an ISO 7 space.

ANSWER:

26. Admit that the documents attached as Exhibit E are true and accurate copies of emails you received from Barry Cadden in the normal course of NECC's business.

ANSWER:

27. Admit that in the email you received from Barry Cadden on Wednesday, August 10, attached as Exhibit E, Barry Cadden stated, "I am told that the lots for some drugs almost never coincide with the available test data."

ANSWER:

28. Admit that in the email you received from Barry Cadden on Wednesday, August 10, attached as Exhibit E, Barry Cadden stated, "I was told that we are only testing rarely and dispensing many untested lots."

ANSWER:

29. Admit that Exhibit F is a true and accurate copy of an email you sent to Barry Cadden on Monday, December 19, 2011.

ANSWER:

30. Admit that the email in Exhibit F was sent in the normal course of NECC's business.

ANSWER:

31. Admit that in the email attached as Exhibit F, you indicated that you were using "MTX" that had expired in 2007 in NECC's injectable products in 2011.

ANSWER:

Respectfully Submitted,

BLUMBERG & WOLK, LLC

/s/ Christopher Wolk

Jay Blumberg
Christopher Wolk
158 Delaware Street
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Woodbury, NJ 08096
(856) 848-7472

Attorneys for the Premier Defendants

CERTIFICATE OF SERVICE

I hereby certify that on this 14th day of May, 2015, a true and accurate copy of the foregoing was served on Glenn Chin by U.S. mail and on the other parties below electronically via the Court's CM/ECF system:

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/s/ Christopher Wolk
Christopher Wolk

EXHIBIT B

Logged Formula Worksheet (standard)

5/21/2012 9:58:08 AM
Page 1

NEW ENGLAND COMPOUNI
697 WAVERLY ST.
697 WAVERLY ST.
FRAMINGHAM, MA 01702 Ph

METHYLPRED. AC (PF) 80MG/ML INJECTABLE

Flavor:
Description:
Quantity made: 12500 ML
Batch yield: 12,500.000
Qty remaining: 12,500.000
Schedule: L
PCCA ID:
Route of admin:
Log ID: 2299384

Date made: 5/21/2012
Lot number: 05212012@68
Beyond use date: November 17, 2012 9:57 AM
180 days after compounding date
Pharmacist: GC
Technician: JOSEPH P CONNOLLY
NDC1:
Packaging:
Equipment:

Pricing calculations fr	
Estimated price	$9.
Ingredient cost	$0.
Device cost	$0.
Time cost	$0.
Profit	

Labeling: SHAKE WELL***SDV***
Stability information:

	Chemicals	Sch.	Quantity used	QS	
1	METHYLPREDNISOLONE ACETATE USP (STERILE) Pt -		1000 GM	☑	
	Lot #: Z8740/A Mfg:		Exp. date: 4/30/2016		
	Chemical Code: Volume: Medisca Potency:		QS amount:		
	Balance: 8/13/14		NDC: 49452-4688-02		
2	POLYETHYLENE GLYCOL 3350 NF (STERILE) BASE -		352.5 GM	☐	$7,755.00 07/21/2005
	Lot #: 77089/A Mfg: MEDISCA		Exp. date: 2/28/2014		Whlsr: MEDISCA
	Chemical Code: Volume: Potency:		QS amount:		AWP: $0.00
	Balance:		NDC:		Each ML contains 0.0282 GM or 2.82% ChemInvID: 0
3	SODIUM CHLORIDE (STERILE) GRANUALE -		28.5 GM	☐	$0.56 04/02/2012
	Lot #: 11020203 Mfg: MEDISCA		Exp. date: 11/10/2013		Whlsr: MEDISCA
	Chemical Code: Volume: Potency:		QS amount:		AWP: $5.13
	Balance:		NDC: 51927108700		Each ML contains 0.00228 GM or 0.228% ChemInvID: 0
	WATER FOR INJECTION INJ		12500 ML	☒	$25,000.00 06/17/2005
	Lot #: J2B670 Mfg: BRAUN		Exp. date: 8/31/2014		Whlsr: BRAUN
	Chemical Code: Volume: Potency:		QS amount:		AWP: $61.13
	Balance:		NDC: 00409488799		Each ML contains 1 ML or 100% ChemInvID: 300
6	POLYSORBATE 80 (STERILE) LIQUID O		47.5 ML	☐	$0.00 04/02/2009
	Lot #: 79814/C Mfg: MEDISCA		Exp. date: 8/31/2013		Whlsr: MEDISCA
	Chemical Code: Volume: Potency:		QS amount:		AWP: $0.00
	Balance:		NDC:		Each ML contains 0.0038 ML or 0.38% ChemInvID: 170
6	SODIUM PHOSPHATE MONOBASIC (STERILE) POWDI -		82.375 GM	☐	$82.38 09/30/2008
	Lot #: 11010925 Mfg: LETCO		Exp. date: 8/11/2013		Whlsr: PROFESSIONAL COMPOUN
	Chemical Code: Volume: Potency:		QS amount:		AWP: $0.00
	Balance:		NDC:		Each ML contains 0.00659 GM or 0.659% ChemInvID: 0
7	SODIUM PHOSPHATE DIBASIC (STERILE) POWDER		17.125 GM	☐	$0.00 11/01/2011
	Lot #: G440892 Mfg: BOCA		Exp. date: 8/4/2012		Whlsr: PROFESSIONAL COMPOUN
	Chemical Code: Volume: JT Baker Potency:		QS amount:		AWP: $0.00
	Balance: K32703		NDC:		Each ML contains 0.00137 GM or 0.137% ChemInvID: 289
			(Added all GM & GMS: 1,480.50)		$32,837.94

Log Instructions & Notes

Originally made as: 12500 METHYLPRED. AC (PF) 80MG/ML INJECTABLE
Calculated lot number: 05212012@68 Beyond use date: 11/17/2012
FORMULA INSTRUCTIONS:

ZEBRA BAR CODES:
99600010504 - 1mL VIAL
99600020504 - 2mL VIAL
99600050504 - 5mL VIAL

Date entered: 5/21/2012 9:57:45 AM Last modified: 5/21/2012 9:58:06 AM by: LAB
Checked by: _____ Date: _____

MODEL No. MLS-[illegible]81

OPERATION DATE 2012/05/21
TIME PM 08:45:12

COURSE 1

CYCLE STARTED

TIME ELAPSED	TEMP CENT.	PRESS kPa	STATUS CYCLE
00:11:58	090.0	14	HEAT
00:13:59	100.0	24	HEAT
00:22:01	106.4	30	HEAT
00:25:25	121.0	104	STERI.
00:27:25	121.8	110	STERI.
00:29:25	121.8	111	STERI.
00:31:25	121.6	109	STERI.
00:33:25	121.7	111	STERI.
00:35:25	121.7	111	STERI.
00:37:25	121.6	110	STERI.
00:39:25	121.7	112	STERI.
00:40:29	121.7	112	COOL
01:14:16	064.9	5	COMPLETE

START TIME PM 08:45:12
END TIME PM 09:59:27

Logged Formula Worksheet (Standard)

6/29/2012 9:06:36 AM
Page 1

NEW ENGLAND COMPOUND
697 WAVERLY ST.
697 WAVERLY ST.
FRAMINGHAM, MA 01702

N + 352.504 g
N + 28.506 g
N + 82.376 g
N + 17.123 g

METHYLPRED. AC (PF) 80MG/ML INJECTABLE

Flavor:
Description:
Schedule: L

Formula ID: 2228
Log ID: 235896

Quantity made: 12500 ML
Batch yield: 12,500.000
Qty remaining: 12,500.000
PCCA ID:
Route of admin:

Date made: 6/29/2012
Lot number: 06292012@26
Beyond use date: December 26, 2012 9:06 AM
180 days after compounding date
Pharmacist: GC
Technician: <NONE>
NDC1:
Packaging:
Equipment:

Pricing calculations from t	
Estimated price	$9.00 as
Ingredient cost	$0.00
Device cost	$0.00
Time cost	$
Profit	$

15L
SB
06-27-12 A11:41 OUT

Labeling: SHAKE WELL***SDV***
Stability information:

teflon
05-24-12 P03:42 OUT

#	Chemicals	Sch.	Quantity used	QS	Details
1	METHYLPREDNISOLONE ACETATE USP (STERILE) PI - Lot #: ~~78740/A~~ 32872/B; Mfg: Medisca; Chemical Code:; Volume:; Potency:; Balance:		2x500g = 1000 GM; Exp. date: ~~4/30/2016~~ 01-30-17; QS amount:; NDC: 49452-4688-02	☐	Whls
2	POLYETHYLENE GLYCOL 3350 NF (STERILE) BASE; Lot #: 77089/A; Mfg: MEDISCA; Chemical Code:; Volume:; Potency:; Balance:	-	352.5 GM; Exp. date: 2/28/2014; QS amount:; NDC:	☐	$7,755.00 07/21/2005; Whlsr: MEDISCA; AWP: $0.00; Each ML contains 0.0282 GM or 2.82%; CheminvID: 0
3	SODIUM CHLORIDE (STERILE) GRANUALE; Lot #: 11020203; Mfg: MEDISCA; Chemical Code:; Volume:; Potency:; Balance:	-	28.5 GM; Exp. date: 11/10/2013; QS amount:; NDC: 51927108700	☐	$0.56 04/02/2012; Whlsr: MEDISCA; AWP: $0.13; Each ML contains 0.00228 GM or 0.228%; CheminvID: 0
4	WATER FOR INJECTION INJ; Lot #: J2A488; Mfg: BRAUN; Chemical Code:; Volume:; Potency:; Balance:		12500 ML; Exp. date: 7/31/2014; QS amount:; NDC: 00409488799	☒	$25,000.00 06/17/2005; Whlsr: BRAUN; AWP: $61.13; Each ML contains 1 ML or 100%; CheminvID: 300
5	POLYSORBATE 80 (STERILE) LIQUID; Lot #: 79814/C; Mfg: MEDISCA; Chemical Code:; Volume:; Potency:; Balance:	O	47.5 ML; Exp. date: 8/31/2018; QS amount:; NDC:	☐	$0.00 04/02/2009; Whlsr: MEDISCA; AWP: $0.00; Each ML contains 0.0038 ML or 0.38%; CheminvID: 170
6	SODIUM PHOSPHATE MONOBASIC (STERILE) POWDI; Lot #: 11010925; Mfg: LETCO; Chemical Code:; Volume:; Potency:; Balance:	-	82.375 GM; Exp. date: 8/11/2013; QS amount:; NDC:	☐	$82.38 09/30/2008; Whlsr: PROFESSIONAL COMPOUN; AWP: $0.00; Each ML contains 0.00659 GM or 0.659%; CheminvID: 0
7	SODIUM PHOSPHATE DIBASIC (STERILE) POWDER; Lot #: ~~C140892~~ X32473; Mfg: ~~PCCA~~ J.T. BAKER; Chemical Code:; Volume:; Potency:; Balance:		17.125 GM; Exp. date: ~~8/1/2013~~ 5-31-2013; QS amount:; NDC:	☐	$0.00 11/01/2011; Whlsr: PROFESSIONAL COMPOUN; AWP: $0.00; Each ML contains 0.00137 GM or 0.137%; CheminvID: 289

(Added all GM & GMS: 1,480.50) $32,837.94

Log Instructions & Notes

Originally made as: 12500 METHYLPRED. AC (PF) 80MG/ML INJECTABLE
Calculated lot number: 06292012@26 Beyond use date: 12/26/2012
FORMULA INSTRUCTIONS:

11 Walgreens
Lot # - 1070553
Exp - Apr'17

ZEBRA BAR CODES:
99600010504 - 1mL VIAL
99600020504 - 2mL VIAL
99600050504 - 5mL VIAL

pH=5.4 (4.4pm) 325(?) UT=60'

Date entered: 6/29/2012 9:06:22 AM Last modified: 6/29/2012 9:06:34 AM by: LAB
Checked by: [signature] Date: 06/28/12

BASE Beaker

necc

06-22-12 P03:05 OUT

BASE S_0 B_0

MODEL No. NLS-3781

OPERATION DATE 2012/06/30
TIME PM 08:01:18

COURSE 1

CYCLE STARTED

TIME ELAPSED	TEMP CENT.	PRESS kPa	STATUS CYCLE
00:09:53	090.0	6	HEAT
00:13:28	100.0	23	HEAT
00:21:30	101.5	10	HEAT
00:25:41	121.0	104	STERI.
00:27:41	121.8	110	STERI.
00:29:41	121.8	110	STERI.
00:31:41	121.8	110	STERI.
00:33:41	121.6	110	STERI.
00:35:41	121.8	112	STERI.
00:37:41	121.7	112	STERI.
00:39:41	121.6	111	STERI.
00:40:46	121.6	114	COOL
01:15:00	064.9	4	COMPLETE

START TIME PM 06:01:18
END TIME PM 09:16:18

Logged Formula Worksheet (standard)
6/29/2012 9:06:36 AM
Page 2

LG235896

NEW ENGLAND COMPOUNDING CTR
697 WAVERLY ST.
697 WAVERLY ST.
FRAMINGHAM, MA 01702 Ph. 800-994-6322

METHYLPRED. AC (PF) 80MG/ML INJECTABLE

Flavor:
Description:
Schedule: L
Active ☑
Formula ID: 2228
Log ID: 235896

Quantity made: 12500 ML
Batch yield: 12,500.000
Qty remaining: 12,500.000
PCCA ID:
Route of admin:

12/09/09 POLYSORBATE-80 DOUBLED FROM 0.194ML/100ML TO 0.38ML/100ML GC

MATERIALS: STERILE BEAKER, STERILE SPIN BAR, STERILE HOMOGENIZER ELEMENT
medisca 500gm plastic bottle weighs 98gms, plastic seal ring weighs 0.7gms
medisca 1kg plastic bottle weighs 145gms, WITH TOP
1) WEIGH CHEMICALS IN STERILE WEIGH CUPS ON ELECTRONIC ANALYTICAL BALANCE
2) IN HOOD DISSOLVE BASE-B, SODIUM PHOSPHATE MONOBASIC, SODIUM PHOSPHATE DIBASIC, SODIUM CHLORIDE, AND POLYSORBATE -80 IN VORTEX OF 80% FINAL VOLUME OF STERILE WATER.FILTER SOLUTION THROUGH A 0.22MICRON NALGENE FILTER.
3) SLOWLY ADD METHYLPREDNISOLONE ACETATE TO VORTEX OF ABOVE SOLUTION.
4) HOMOGENIZE AT HIGH SPEED FOR 2-5 MINUTES (VOLUME DEP.)
5) QS TO FINAL VOLUME WITH STERILE WATER FOR INJECTION.
6) COVER WITH MULTIPLE LAYERS OF FOIL AND SEAL WITH AUTOCLAVE INDICATOR TAPE
7) AUTOCLAVE AT 121C-15PSI-20MIN
####SPRAY EXTERIOR OF SEALED BEAKER WITH 70% IPA######
8) RETURN TO HOOD AND REHOMOGENIZE. CREATE VORTEX AND ALLOW TO SOIN TILL COOLED TO ROOM TEMP.
9) FILL STERILE AMBER VIALS USING BAXA REPEATER PUMP VIA DISPOSABLE STERILE TUBING
10) CAP ,CRIMP, AND LABEL

####PULL RANDOM VIALS FOR APPROPRIATE ANALYSIS######

Date entered: 6/29/2012 9:06:22 AM Last modified: 6/29/2012 9:06:34 AM by: LAB
Checked by: _____ Date: ____/____/_____

Logged Formula Worksheet (standard)

8/10/2012 2:43:06 PM
Page 1

LG2122 94

NEW ENGLAND COMPOUN
697 WAVERLY ST.
697 WAVERLY ST.
FRAMINGHAM, MA 01702

N + 352.506 g
N + 28.501 g
N + 82.377 g
N + 17.129 g

METHYLPRED. AC (PF) 80MG/ML INJECTABLE

Flavor:
Description:
Schedule: L
Active ☑
Formula ID: 2228

Quantity made: 12500 ML
Batch yield: 12,500.000
Qty remaining: 12,500.000
PCCA ID:
Route of admin:

Date made: 8/10/2012
Lot number: 08102012@51
Beyond use date: February 6, 2013 2:42 PM
180 days after compounding date
Pharmacist: GC
Technician: JOSEPH P CONNOLLY
NDC1:
Packaging:
Equipment:

Pricing calculations from the l	
Estimated price	$9.00 as of
Ingredient cost	$0.00
Device cost	$0
Time cost	$0
Profit	$9

08-07-12 A11:42 OUT

Labeling: SHAKE WELL***SDV***
Stability information:

Chemicals	Sch.	Quantity used	QS	(Balance)
1 METHYLPREDNISOLONE ACETATE USP (STERILE) P(- 2 x 500 gm =		1000 GM	☐	
Lot #: 78740/A Mfg: Volume: Potency: Exp. date: 4/30/2016 QS amount:				Whlsr:
Chemical Code: Balance: 8113/6 + 80494/B Medisca		09-30-16 + 09-30-16		Each
NDC: 49452-4689-02				
POLYETHYLENE GLYCOL 3350 NF (STERILE) BASE -		352.5 GM	☐	
Lot #: 76985/A Mfg: MEDISCA Exp. date: 8/31/2013				Whlsr:
Chemical Code: Volume: Potency: QS amount: Balance:				Each
NDC: ChemInvID: 0				
SODIUM CHLORIDE (STERILE) GRANULE -		28.5 GM	☐	$0.56 4/2/2012
Lot #: 11020203 Mfg: MEDISCA Exp. date: 11/10/2013				Whlsr: MEDISCA
Chemical Code: Volume: Potency: QS amount: Balance:				AWP: $5.13
NDC: 51927108700				Each ML contains 0.00228 GM or 0.228% ChemInvID: 0
WATER FOR INJECTION INJ		12500 ML	☒	$25,000.00 6/17/2005
Lot #: J2B670 Mfg: BRAUN Exp. date: 8/31/2014				Whlsr: BRAUN
Chemical Code: Volume: Potency: QS amount: Balance:				AWP: $81.13
NDC: 00409488799				Each ML contains 1 ML or 100% ChemInvID: 300
5 POLYSORBATE 80 (STERILE) LIQUID O		47.5 ML	☐	$0.00 4/2/2009
Lot #: 79814/C Mfg: MEDISCA Exp. date: 8/31/2013				Whlsr: MEDISCA
Chemical Code: Volume: Potency: QS amount: Balance:				AWP: $0.00
NDC:				Each ML contains 0.0030 ML or 0.30% ChemInvID: 170
SODIUM PHOSPHATE MONOBASIC (STERILE) POWDI -		82.375 GM	☐	$82.38 9/30/2008
Lot #: 11010925 Mfg: LETCO Exp. date: 8/11/2013				Whlsr: PROFESSIONAL COMPOUN
Chemical Code: Volume: Potency: QS amount: Balance:				AWP: $0.00
NDC:				Each ML contains 0.00659 GM or 0.659% ChemInvID: 0
SODIUM PHOSPHATE DIBASIC (STERILE) POWDER		17.125 GM	☐	$0.00 11/1/2011
Lot #: G140892 Mfg: PCCA Exp. date: 8/11/2013				Whlsr: PROFESSIONAL COMPOUN
Chemical Code: Volume: 5 To BAKER Potency: QS amount: 08-31-2013 Balance: K39H09				AWP: $0.00
NDC:				Each ML contains 0.00137 GM or 0.137% ChemInvID: 289
		(Added all GM & GMS: 1,480.50)		$32,837.94

Log Instructions & Notes

Originally made as: 12500 METHYLPRED. AC (PF) 80MG/ML INJECTABLE
Calculated lot number: 08102012@51 Beyond use date: 2/6/2013
FORMULA INSTRUCTIONS:

ZEBRA BAR CODES:
99600010504 - 1mL VIAL
99600020504 - 2mL VIAL
99600050504 - 5mL VIAL

pH = 5 w/ phos 4°C = 72' Syr (9)

Date entered: 8/10/2012 2:42:54 PM Last modified: 8/10/2012 2:43:04 PM by: LAB
Checked by: Date: 08/30/2012

EXHIBIT C

advancing pharmacy solutions
NECC

697 Waverly Street, Framingham, MA 01702
Tel: 800.994.6322 or 508.820.0606
Fax: 888.820.0583 or 508.820.1616
www.neccrx.com

General Overview of Policies & Procedures for Compounding Sterile Products

NECC operates in accordance with the following general guidelines when compounding sterile products:

A. Facility/Equipment

a. ISO-5 & ISO-6 Cleanroom(s).
b. Class 10 Microenvironments (barrier isolator).
c. Certified by Massachusetts Board of Pharmacy as a pharmacy with a central venous admixture service (CIVAS) in accordance with Board regulations, 247 CMR 6.01 (6)(c).

B. Monitoring & Maintenance

Comprehensive environmental monitoring program

a. All cleanroom space, air, surfaces and hoods are sampled on a weekly basis, exceeding USP 797.

C. Personnel

a. All sterile compounding is performed by properly trained and validated registered pharmacists.
b. Pharmacy personnel are trained/validated by an outside agency, Professional Compounding Centers of America (PCCA).
c. Personnel are validated on a quarterly basis.

D. Quality Assurance/Quality Control

a. USP Chemicals are obtained only from FDA registered facilities.
b. Formulations are sterilized by 0.22 micron filtration or by autoclaving.
c. Samples from final product batch lots are sent to an independent FDA registered analytical lab for sterility, endotoxin (pyrogenicity) and potency testing.
d. Tested medication is quarantined and dispensed only after the sample has tested negative for endotoxin and microbial contamination.

e. The Quality Assurance Team (QAT), made up of employees from all departments within NECC, meets regularly to review all quality related items.
f. NECC maintains strict environmental testing protocols. Results of these tests are reported via Quarterly QA Reports.
g. All sterile compounding actions are performed in compliance with NECC's Standard Operating Procedures (SOPs). These SOPs have been "mapped" against USP 797 "Pharmaceutical Compounding – sterile preparations" to ensure that all USP 797 requirements are observed.

E. Use-by Dating

Each dosage form is labeled with a BUD/expiration date appropriate to the formulation obtained from:

a. Current literature.
b. Independent stability assay.

F. Packaging

a. Compounded preparations are packaged in containers meeting USP standards.
b. Container used depends on the physical and chemical properties of the compounded preparation.

G. Dispensing

There must be a specific practitioner-patient-pharmacist relationship in place to dispense to an individual patient or facility.

H. Shipping

Medications are shipped overnight (usually via FedEx) in an appropriate container to ensure controlled temperatures and product integrity.

I. Licensing

NECC has undertaken a rigorous licensure process thus giving us the ability to legally dispense prescription medication in all 50 states.

EXHIBIT D

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Certificate Of Analysis

CLIENT: New England Compounding Center-MA

ARL #: 176896-01
LOT #: 05212012@68
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 05/22/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Methylprednisolone Acetate Specifications = 90% - 110%	80	mg/mL	83.604	104.5%	HPLC	5/23/2012

alex tang - Laboratory Supervisor

05/24/2012
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: New England Compounding Center-MA

ARL #: 176896-01
LOT #: 05212012@68
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 05/22/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	Sterile	USP 71	05/22/2012
Endotoxin	6.25 EU/mg	<0.05 EU/mg	USP 85	05/23/2012

Amar Arafat - Microbiologist

06/05/2012
Date Reported

Sterility - 14 day sterility report. In accordance with the USP guidelines, the samples will be incubated for 14 days.

Results reported above relate only to the sample that was tested.

ARL Form QUF-078-V4 03/05/2010

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: New England Compounding Center-MA

ARL #: 176896-01
LOT #: 05212012@68
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 05/22/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility (*Preliminary*)	Sterile / Not Sterile	Sterile	USP 71	05/22/2012
Endotoxin	6.25 EU/mg	<0.05 EU/mg	USP 85	05/23/2012

Sterility - This preliminary report was issued after approximately 72 hours of incubation. In accordance with the USP guidelines, the samples will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Fungal - This preliminary report was issued after 4-5 days of incubation. In accordance with the USP guidelines, the samples will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Endotoxin - To calculate the endotoxin limit use the following formulae: EL = K/M where K = tolerance limit (EU/kg) and M = Maximum dose/kg/hour or Maximum dose/kg
Parenteral: K is 5 EU/kg for any route of administration /Intrathecal: K is 0.2 EU/kg body weight)
Radiopharmaceutical parenteral: K is 175/Y or Intrathecal radiopharmaceuticals: K is 14/V, where V is the maximum recommended dose in mL.
Dermal Application: K/M, where K = 5 EU/kg and M is the (maximum dose/m2/hour × 1.80 m2)/70 Kg.

Amar Arafat - Microbiologist

05/25/2012
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Certificate Of Analysis

CLIENT: New England Compounding Center-MA

ARL #: 180509-01
LOT #: 06292012@26
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 07/03/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Methylprednisolone Acetate Specifications = 90% - 110%	80	mg/mL	81.451	101.8%	HPLC	7/5/2012

Alex Tang - Laboratory Supervisor

07/05/2012
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: New England Compounding Center-MA

ARL #: 180509-01
LOT #: 06292012@26
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 07/03/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	Sterile	USP 71	07/03/2012
Endotoxin	6.25 EU/mg	<0.05 EU/mg	USP 85	07/06/2012

Sample properties cause turbidity in growth media. Per USP 71; the sample will be inoculated into new growth media after 14 days of incubation and incubated for 4 additional days.

Amar Arafat - Microbiologist

07/17/2012
Date Reported

Sterility - 14 day sterility report. In accordance with the USP guidelines, the samples will be incubated for 14 days.

Results reported above relate only to the sample that was tested.

ARL Form QUF-078-V4 03/05/2010

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: New England Compounding Center-MA

ARL #: 180509-01
LOT #: 06292012@26
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 07/03/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility (*Preliminary*)	Sterile / Not Sterile	Sterile	USP 71	07/03/2012
Endotoxin	6.25 EU/mg	<0.05 EU/mg	USP 85	07/06/2012

Sterility - This preliminary report was issued after approximately 72 hours of incubation. In accordance with the USP guidelines, the samples will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Fungal - This preliminary report was issued after 4-5 days of incubation. In accordance with the USP guidelines, the samples will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Endotoxin - To calculate the endotoxin limit use the following formulae: EL = K/M where K = tolerance limit (EU/kg) and M = Maximum dose/kg/hour or Maximum dose/kg
Parenteral: K is 5 EU/kg for any route of administration /Intrathecal: K is 0.2 EU/kg body weight)
Radiopharmaceutical parenteral: K is 175/V or Intrathecal radiopharmaceuticals: K is 14/V, where V is the maximum recommended dose in mL.
Dermal Application: K/M, where K = 5 EU/kg and M is the (maximum dose/m2/hour × 1.80 m2)/70 Kg.

Amar Arafat

Amar Arafat - Microbiologist

07/06/2012
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Certificate Of Analysis

CLIENT: New England Compounding Center
697 Waverly Street
Framingham, MA 01702

ARL #: 184460-01
LOT #: 08102012@51
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 08/14/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL clear vials

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Methylprednisolone Acetate Specifications = 90% - 110%	80	mg/mL	81.676	102.1%	HPLC	8/15/2012

Alex Tang - Laboratory Supervisor

08/15/2012
Date

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Certificate Of Analysis

CLIENT: New England Compounding Center
697 Waverly Street
Framingham, MA 01702

ARL #: 184460-01
LOT #: 08102012@51
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 08/14/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL clear vials

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Methylprednisolone Acetate Specifications = 90% - 110%	80	mg/mL	81.676	102.1%	HPLC	8/15/2012

Alex Tang - Laboratory Supervisor

08/15/2012
Date

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: New England Compounding Center

ARL #: 184460-01
LOT #: 08102012@51
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 08/14/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL clear vials

ANALYSIS	Limits	Results	Test Method	Date Tested
Endotoxin	6.25 EU/mg	<0.05 EU/mg	USP 85	08/16/2012

Sample properties cause turbidity in growth media. Per USP 71, the sample will be inoculated into new growth media after 14 days of incubation and incubated for 4 additional days.

Tiffany O. Hyde

Tiffany Hyde - Microbiologist

08/17/2012
Date Reported

Sterility – This preliminary report was issued after approximately 72 hours of incubation. In accordance with the USP guidelines, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Fungal – This preliminary report was issued after approximately 4 days of incubation. In accordance with the USP guidelines, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Endotoxin - To calculate the endotoxin limit use the following formulae: EL = K/M where K = tolerance limit (EU/kg) and M = Maximum dose/kg/hour or Maximum dose/kg
Parenteral: K is 5 EU/kg for any route of administration /Intrathecal: K is 0.2 EU/kg body weight)
Radiopharmaceutical parenteral: K is 175/V or Intrathecal radiopharmaceuticals: K is 14/V, where V is the maximum recommended dose in mL.
Dermal Application: K/M, where K = 5 EU/kg and M is the (maximum dose/in2/hour × 1.80 in2)/70 Kg.

Results reported above relate only to the sample that was tested.

ARL Form QUF-078-V5 08/20/2012

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: New England Compounding Center
697 Waverly Street
Framingham, MA 01702

ARL #: 184460-01
LOT #: 08102012@51
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 08/14/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL clear vials

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	No Growth at 14 Days	USP 71	08/14/2012

Sample properties cause turbidity in growth media. Per USP 71, the sample will be inoculated into new growth media after 14 days of incubation and incubated for 4 additional days.

Tiffany D. Hyde

Tiffany Hyde - Microbiologist

08/28/2012
Date Reported

Sterility – 14 day sterility report. In accordance with the USP guidelines, the sample was incubated for 14 days.

Fungal – 14 day fungal report. In accordance with the USP guidelines, the sample was incubated for 14 days.

Results reported above relate only to the sample that was tested.

ARL Form QUF-078-V5 08/20/2012

EXHIBIT E

From: Barry Cadden </O=FIRST ORGANIZATION/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BCADDEN>
Sent: Wednesday, August 10, 2011 10:37 AM
To: Glenn Chin <gchin@neccrx.com>
Subject:

What's the testing process for the large volume meds currently? I assumed that we have at least sterility testing for "all" lots of large volume injectable lots that we are dispensing but I am told that the lots for some drugs almost never coincide with the available test data. Is this true? You need to run like normal stock meds like beta repos = test every lot and just fill as you go based on the size vial + # needed or make as many lots as you like "internally" but only label vials with lot# of tested lots to cover our ass =ex.. Avastin. I was told that we are only testing rarely and dispensing many untested lots? Please clear this up + tell me what we are doing + will do. Botton line is we can't be caught with our pants at our ankles....ever.

From: Barry Cadden </O=FIRST ORGANIZATION/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BCADDEN>
Sent: Tuesday, May 22, 2012 1:50 PM
To: Glenn Chin <gchin@neccrx.com>
Subject:

This situation is exactly why Scott must be swapped into a less dangerous position! We would be fucked if this was a cardio med!!!.....

From: Barry Cadden </O=FIRST ORGANIZATION/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BCADDEN>
Sent: Tuesday, August 7, 2012 9:16 AM
To: Glenn Chin <gchin@neccrx.com>
Subject:

The "problem" CP order has my name as sign in for pump!....we need to get Scott out of that room or at least off the sign in by tomorrow. Have him be there , help, train...etc but someone else MUST sign in .....I have no idea how I am going to explain this situation but it can't continue beyong today.....see me later

thanks

From: Barry Cadden
Sent: Tuesday, July 03, 2012 2:20 PM
To: Glenn Chin
Subject:

What's going on with the materials (mops..etc) for the Uniclean, cleaning people? How are they being handled? ...I ask because we have another fungal bloom on June-28th=day of last cleaning. Are the pharmacists watching these idiots or sleeping? We need to keep an eye on them + make sure that the mops..etc are not contaminated. I am getting the film again so we can check it out.....

EXHIBIT F

From: Glenn Chin </O=FIRST ORGANIZATION/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=GCHIN>
Sent: Monday, December 19, 2011 11:36 AM
To: Barry Cadden <bcadden@neccrx.com>; Cory Fletcher <cfletcher@neccrx.com>
Subject: RE: MTX

We have about 1.25KG of MTX left. It's the old Spectrum bottles. When I say old I mean OLD, it expired in 2007 according to their sticker. We make it for our injectables and we send it out for testing and it comes out pretty close. We generally under QS the lot's we make. I would probably guess that it's at about 90 to 95% potent.

From: Barry Cadden
Sent: Monday, December 19, 2011 9:32 AM
To: Glenn Chin; Gene Svirskiy; Cory Fletcher
Subject: MTX

How much MTX powder to we have in house? I am hearing that there is another backorder of commercial inj. MTX + can't find a chemical co. who has any powder in stock

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	MDL No. 2419 Dkt. No: 1:13-md-2419-RWZ
THIS DOCUMENT RELATES TO: Suits Naming the Premier Defendants	

THE PREMIER DEFENDANTS' FIRST INTERROGATORIES, REQUESTS FOR PRODUCTION OF DOCUMENTS, AND REQUESTS FOR ADMISSION PROPOUNDED TO CARLA CONIGLIARO.

Come the Defendants, Premier Orthopaedic and Sports Medicine Associates of Southern New Jersey, LLC, trading as Premier Orthopaedic Associates; Premier Orthopaedic Associates Surgical Center, LLC; Kimberly Yvette Smith, M.D., a/k/a Kimberly Yvette Smith-Martin, M.D.; Thomas Dwyer, M.D.; Richard C. DiVerniero, M.D.; and Richard Strauss, M.D. (collectively, "Premier Defendants") , pursuant to Rules 26, 33, and 34 of the Federal Rules of Civil Procedure and the Local Rules for the District of Massachusetts, and propound the following Interrogatories, Requests for Production of Documents, and Requests for Admission to Carla Conigliaro.

Each of the following Interrogatories shall be answered under oath, in writing, separately, to the fullest possible detail, and in accordance with the definitions and instructions set forth below. The answers shall be signed by the person making them, and a copy of the answers, together with objections, if any, shall be served within thirty (30) days after the service date of these interrogatories.

You are under a duty to seasonably supplement your response with respect to any Interrogatory directly addressed to the identity and location of persons having knowledge of discoverable matters. You are under a duty to amend a prior response if you obtain information on the basis of which you know that the response was incorrect when made, or that the response, though correctly made, is no longer true, and the circumstances are such that a failure to amend the response is, in substance, a knowing concealment.

DEFINITIONS

1. As used in this document, the terms "person(s)" and "individual(s)" mean any natural individual in any capacity whatsoever or any entity or organization, including divisions, departments, and other units therein, and shall include, but not be limited to, a public or private corporation, partnership, joint venture, voluntary or unincorporated association, organization, proprietorship, trust, estate, governmental agency, commission, bureau, or department.

2. As used in this document, the term "document" means any medium upon which intelligence or information can be recorded or retrieved, and includes without limitation, the original and each copy, regardless of origin and location, of any book, pamphlet, periodical, letter, memorandum (including any memorandum or report of a meeting or conversation), invoice, bill, order form, receipt, financial statement, accounting entry, diary, calendar, telex, telegram, cable, report, record, contract, agreement, study, handwritten note, draft, working paper, chart, paper, print, laboratory record, drawing or sketch, graph, index, lists, tape, photograph, microfilm, data sheet or data processing card, or any other written, recorded, transcribed, punched, taped, filmed, or graphic matter, however produced or reproduced, which is in your possession, custody, or control, or which was, but is no longer, in your possession, custody, or control.

3. As used in this document, the terms "identification," "identify," or "identity," when used in reference to a natural individual, require you to state his or her full name and residential and business address. Use of the term "document" in connection with the Interrogatories requires you to state the number of pages and the nature of the document, its title, its date, the name or names of its authors, and recipients, and its present location and custodian.

4. "You and "your" refers to Carla Conigliaro and each of her present and former agents, representatives, and employees, attorneys and accountants, and each person acting or purporting to act on her behalf.

5. "Communication" means any oral or written utterance, notification, or statement of any nature whatsoever, by and to whomsoever made, including, but not limited to, correspondence, conversation, dialogue, discussions, interviews, consultants, and any other understanding between or among two or more persons.

INSTRUCTIONS

1. With respect to each Interrogatory, in addition to answering the question, you are to identify all documents that support, refer to, or evidence the subject matter of each Interrogatory and your answer thereto.

   If any or all identified documents are no longer in your possession, custody, or control because of destruction, loss, or any other reason, then you must do the following with respect to each and every document:

   A. Describe the nature of the document;

   B. State the date of the document;

   C. Identify the persons who sent and received the original and the copy of the document;

   D. State in as much detail as possible the contents of the documents; and

   E. State the manner and date of disposition of the document.

   If you contend that you are entitled to withhold from production any or all documents identified herein on the basis of attorney-client privilege, the work-product doctrine, or any other ground, then do the following with respect to each and every document:

   A. Describe the nature of the document;

   B. State the date of the document;

   C. Identify the persons who sent and received the original and a copy of the document;

   D. State the subject matter of the document; and

   E. State the basis upon which you contend you are entitled to withhold the document from production.

2. All documents produced should be organized and labeled to correspond to the specific Request in response to which they are being made available or should be produced as they are kept in the usual course of business.

3. The terms "and," "or," and "and/or" should be construed either disjunctively or conjunctively so as to bring within the scope of these Interrogatories and Requests any information that might otherwise be construed as outside their scope.

4. The term "any" should be construed to include the word "all," and "all" should be construed to include "any."

5. The present tense should be construed to include the past tense, and the past tense should be construed to include the present tense.

6. The singular should be construed to include the plural, and the plural should be construed to include the singular.

7. The terms "he" and "his" should be construed to include the words "she" and "her" or "hers," respectively and vice versa.

8. "Relating to," when referring to a document shall mean mentioning, describing, connected to or with, or discussing the stated subject matter.

INTERROGATORIES

1. Describe in detail your role at NECC and Ameridose, including job title, job description, and a description of your daily duties and activities in 2011 and 2012.

ANSWER:

2. Describe in detail the steps NECC took to compound, process, stopper, seal, package, and ship methylprednisolone acetate ("MPA") in 2011 and 2012, including but not limited to:

   a) The names of the individuals performing each step;

   b) The job titles for the individuals performing each step;

   c) The specific cleanroom or location in NECC's facility where each step took place;

   d) The tools, equipment, or machinery used for each step;

   e) Any changes to NECC's methods or procedures for compounding MPA, or the location where compounding MPA took place, that occurred in 2011 or 2012.

ANSWER:

3. Identify the total amount of MPA that NECC, and separately Ameriose, produced in each quarter of 2010, 2011, and 2012.

ANSWER:

4. Identify the types of vials and closures NECC used for MPA lots numbered 05212012@68, 06292012@26, and 08102012@51 (collectively "Contaminated Lots"), including whether the vials and enclosures were prewashed or presterilized, and identify their manufacturer(s).

ANSWER:

5. Identify any and all complaints that NECC and Ameridose received related to the sterility or safety of their products, including but not limited to complaints by customers, current and former employees, and state and federal government agencies.

ANSWER:

6. Identify any customers of NECC and Ameridose who performed site visits prior to placing orders with either company.

ANSWER:

7. Describe any policies, procedures, or protocols relating to or regarding customer site visits to the NECC facility, including the areas you allowed customers to inspect.

ANSWER:

8. Identify any customers who asked for information about prior recalls of NECC and Ameridose products prior to placing orders with either company.

ANSWER:

9. Identify and describe any information you gave customers about recalled NECC and Ameridose products in 2011 and 2012.

ANSWER:

10. Identify any and all complaints NECC or Ameridose received related to their compliance with state or federal laws and regulations, including but not limited to complaints by customers, current and former employees, and state and federal government agencies.

ANSWER:

11. Identify and describe any way in which NECC's cleanrooms were modified, altered, or expanded by NECC or Ameridose.

ANSWER:

12. Identify any policies, procedures, or guidelines in place at NECC in 2012 that encouraged employees to disclose mistakes in the compounding process, even if the mistakes necessitated destruction of product or halting production.

ANSWER:

13. Describe all disciplinary or enforcement action taken against NECC or Ameridose by any state or federal government agency.

ANSWER:

14. Describe in detail Lisa Conigliaro Cadden's role at NECC in 2011 and 2012.

ANSWER:

VERIFICATION

STATE OF NEW JERSEY)
)
County of _____)

I, _____, after being duly sworn, hereby make oath that the foregoing answers to Interrogatories are true to the best of my knowledge, information, and belief.

_____

Sworn and subscribed before me this _____ day of _____, 2015.

_____
Notary Public

My commission expires on: _____.

REQUESTS FOR PRODUCTION

1. Produce all correspondence between you and any of the Premier Defendants, their employees, agents, or representatives.

RESPONSE:

2. Produce all correspondence and documents referring or related to the Premier Defendants' purchase of MPA from NECC in 2011 or 2012.

RESPONSE:

3. Produce all documents produced by the government to you during any civil, criminal, or administrative proceedings related to NECC's contaminated MPA.

RESPONSE:

4. Produce all policies, procedures, guidelines, instructions and training documents referring or relating to the compounding of MPA at the NECC facility.

RESPONSE:

5. Produce all documents referring or relating to NECC or Ameridose sending samples of insufficient size or volume to comply with USP 71 to ARL or any other testing laboratory.

RESPONSE:

6. Produce all documents referring or relating to any sterility, potency, endotoxin, or fungal testing that you received from ARL or any other laboratory related to MPA compounded by NECC or Ameridose in 2011 and 2012.

RESPONSE:

7. Produce all correspondence and documents referring or relating to fungal blooms or growth in or near NECC's cleanrooms.

RESPONSE:

8. Produce all documents referring or relating to complaints or communications with Liberty Industries regarding the design, manufacture, or installation of the clean rooms at the NECC facility.

RESPONSE:

9. Produce all documents referring or relating to any complaints that NECC or Ameridose received related to the sterility or safety of their products, including but not limited to complaints by customers, current or former employees, or state or federal government agencies.

RESPONSE:

10. Produce all documents referring or relating to any complaints NECC or Ameridose received related to their compliance with state or federal laws or regulations, including but not limited to complaints by customers, current or former employees, or state or federal government agencies.

RESPONSE:

11. Produce all correspondence and documents referring or relating to NECC's response to the meningitis outbreak, including but not limited to, steps NECC took to prepare for any inspections of its facility.

RESPONSE:

12. Produce all training and instructional material for sales staff at NECC or MSM.

RESPONSE:

13. Produce copies of any and all New Jersey Pharmacy Licenses issued to NECC and/or Carla Conigliaro, and all documents or communications between NECC and/or Carla Conigliaro and the New Jersey Board of Pharmacy, including those referring or related to the procurement or renewal of said Licenses.

RESPONSE:

REQUESTS FOR ADMISION

1. Admit that, had any of the Premier Defendants asked for a copy of NECC's license in 2011, you would have provided a valid and up-to-date New Jersey pharmacy license.

ANSWER:

2. Admit that NECC represented to its customers, including the Premier Defendants, that it met or exceeded USP 797 standards.

ANSWER:

3. Admit that NECC represented to its customers, including the Premier Defendants, that its products, including MPA, were safe and sterile.

ANSWER:

4. Admit that the Massachusetts Board of Pharmacy ("Mass. BoP") inspected NECC on or about May 24, 2011.

ANSWER:

5. Admit that as a result of its inspection on or about May 24, 2011, the Mass. BoP issued an inspection report documenting its findings.

ANSWER:

6. Admit that NECC failed to submit a copy of the Mass. BoP's May 24, 2011 inspection report to the New Jersey Board of Pharmacy.

ANSWER:

7. Admit that NECC owed a duty to its customers to ensure that its MPA was sterile prior to distributing it.

ANSWER

Respectfully Submitted,

BLUMBERG & WOLK, LLC

/s/ Christopher Wolk

Jay Blumberg
Christopher Wolk
158 Delaware Street
P.O. Box 68
Woodbury, NJ 08096
(856) 848-7472

Attorneys for the Premier Defendants

CERTIFICATE OF SERVICE

I hereby certify that on this 14th day of May, 2015, a true and accurate copy of the foregoing was served on Carla Conigliaro by U.S. mail and on the other parties below electronically via the Court's CM/ECF system:

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Attorneys for the Saint Thomas Entities

/s/ Christopher Wolk
Christopher Wolk

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	MDL No. 2419 Dkt. No: 1:13-md-2419-RWZ
THIS DOCUMENT RELATES TO: Suits Naming the Premier Defendants	

THE PREMIER DEFENDANTS' FIRST INTERROGATORIES, REQUESTS FOR PRODUCTION OF DOCUMENTS, AND REQUESTS FOR ADMISSION PROPOUNDED TO DOUGLAS CONIGLIARO.

Come the Defendants, Premier Orthopaedic and Sports Medicine Associates of Southern New Jersey, LLC, trading as Premier Orthopaedic Associates; Premier Orthopaedic Associates Surgical Center, LLC; Kimberly Yvette Smith, M.D., a/k/a Kimberly Yvette Smith-Martin, M.D.; Thomas Dwyer, M.D.; Richard C. DiVerniero, M.D.; and Richard Strauss, M.D. (collectively, "Premier Defendants") , pursuant to Rules 26, 33, and 34 of the Federal Rules of Civil Procedure and the Local Rules for the District of Massachusetts, and propound the following Interrogatories, Requests for Production of Documents, and Requests for Admission to Douglas Conigliaro.

Each of the following Interrogatories shall be answered under oath, in writing, separately, to the fullest possible detail, and in accordance with the definitions and instructions set forth below. The answers shall be signed by the person making them, and a copy of the answers, together with objections, if any, shall be served within thirty (30) days after the service date of these interrogatories.

You are under a duty to seasonably supplement your response with respect to any Interrogatory directly addressed to the identity and location of persons having knowledge of discoverable matters. You are under a duty to amend a prior response if you obtain information on the basis of which you know that the response was incorrect when made, or that the response, though correctly made, is no longer true, and the circumstances are such that a failure to amend the response is, in substance, a knowing concealment.

DEFINITIONS

1. As used in this document, the terms "person(s)" and "individual(s)" mean any natural individual in any capacity whatsoever or any entity or organization, including divisions, departments, and other units therein, and shall include, but not be limited to, a public or private corporation, partnership, joint venture, voluntary or unincorporated association, organization, proprietorship, trust, estate, governmental agency, commission, bureau, or department.

2. As used in this document, the term "document" means any medium upon which intelligence or information can be recorded or retrieved, and includes without limitation, the original and each copy, regardless of origin and location, of any book, pamphlet, periodical, letter, memorandum (including any memorandum or report of a meeting or conversation), invoice, bill, order form, receipt, financial statement, accounting entry, diary, calendar, telex, telegram, cable, report, record, contract, agreement, study, handwritten note, draft, working paper, chart, paper, print, laboratory record, drawing or sketch, graph, index, lists, tape, photograph, microfilm, data sheet or data processing card, or any other written, recorded, transcribed, punched, taped, filmed, or graphic matter, however produced or reproduced, which is in your possession, custody, or control, or which was, but is no longer, in your possession, custody, or control.

3. As used in this document, the terms "identification," "identify," or "identity," when used in reference to a natural individual, require you to state his or her full name and residential and business address. Use of the term "document" in connection with the Interrogatories requires you to state the number of pages and the nature of the document, its title, its date, the name or names of its authors, and recipients, and its present location and custodian.

4. "You and "your" refers to Douglas Conigliaro and each of his present and former agents, representatives, and employees, attorneys and accountants, and each person acting or purporting to act on his behalf.

5. "Communication" means any oral or written utterance, notification, or statement of any nature whatsoever, by and to whomsoever made, including, but not limited to, correspondence, conversation, dialogue, discussions, interviews, consultants, and any other understanding between or among two or more persons.

INSTRUCTIONS

1. With respect to each Interrogatory, in addition to answering the question, you are to identify all documents that support, refer to, or evidence the subject matter of each Interrogatory and your answer thereto.

   If any or all identified documents are no longer in your possession, custody, or control because of destruction, loss, or any other reason, then you must do the following with respect to each and every document:

   A. Describe the nature of the document;

   B. State the date of the document;

   C. Identify the persons who sent and received the original and the copy of the document;

   D. State in as much detail as possible the contents of the documents; and

   E. State the manner and date of disposition of the document.

   If you contend that you are entitled to withhold from production any or all documents identified herein on the basis of attorney-client privilege, the work-product doctrine, or any other ground, then do the following with respect to each and every document:

   A. Describe the nature of the document;

   B. State the date of the document;

   C. Identify the persons who sent and received the original and a copy of the document;

   D. State the subject matter of the document; and

   E. State the basis upon which you contend you are entitled to withhold the document from production.

2. All documents produced should be organized and labeled to correspond to the specific Request in response to which they are being made available or should be produced as they are kept in the usual course of business.

3. The terms "and," "or," and "and/or" should be construed either disjunctively or conjunctively so as to bring within the scope of these Interrogatories and Requests any information that might otherwise be construed as outside their scope.

4. The term "any" should be construed to include the word "all," and "all" should be construed to include "any."

5. The present tense should be construed to include the past tense, and the past tense should be construed to include the present tense.

6. The singular should be construed to include the plural, and the plural should be construed to include the singular.

7. The terms "he" and "his" should be construed to include the words "she" and "her" or "hers," respectively and vice versa.

8. "Relating to," when referring to a document shall mean mentioning, describing, connected to or with, or discussing the stated subject matter.

INTERROGATORIES

1. Describe in detail your role at NECC and Ameridose, including job title, job description, and a description of your daily duties and activities in 2011 and 2012.

ANSWER:

2. Describe in detail the steps NECC took to compound, process, stopper, seal, package, and ship methylprednisolone acetate ("MPA") in 2011 and 2012, including but not limited to:

   a) The names of the individuals performing each step;

   b) The job titles for the individuals performing each step;

   c) The specific cleanroom or location in NECC's facility where each step took place;

   d) The tools, equipment, or machinery used for each step;

   e) Any changes to NECC's methods or procedures for compounding MPA, or the location where compounding MPA took place, that occurred in 2011 or 2012.

ANSWER:

3. Identify the total amount of MPA that NECC, and separately Ameriose, produced in each quarter of 2010, 2011, and 2012.

ANSWER:

4. Identify the types of vials and closures NECC used for MPA lots numbered 05212012@68, 06292012@26, and 08102012@51 (collectively "Contaminated Lots"), including whether the vials and enclosures were prewashed or presterilized, and identify their manufacturer(s).

ANSWER:

5. Identify any and all complaints that NECC and Ameridose received related to the sterility or safety of their products, including but not limited to complaints by customers, current and former employees, and state and federal government agencies.

ANSWER:

6. Identify any customers of NECC and Ameridose who performed site visits prior to placing orders with either company.

ANSWER:

7. Describe any policies, procedures, or protocols relating to or regarding customer site visits to the NECC facility, including the areas you allowed customers to inspect.

ANSWER:

8. Identify any customers who asked for information about prior recalls of NECC and Ameridose products prior to placing orders with either company.

ANSWER:

9. Identify and describe any information you gave customers about recalled NECC and Ameridose products in 2011 and 2012.

ANSWER:

10. Identify any and all complaints NECC or Ameridose received related to their compliance with state or federal laws and regulations, including but not limited to complaints by customers, current and former employees, and state and federal government agencies.

ANSWER:

11. Identify and describe any way in which NECC's cleanrooms were modified, altered, or expanded by NECC or Ameridose.

ANSWER:

12. Identify any policies, procedures, or guidelines in place at NECC in 2012 that encouraged employees to disclose mistakes in the compounding process, even if the mistakes necessitated destruction of product or halting production.

ANSWER:

13. Describe all disciplinary or enforcement action taken against NECC or Ameridose by any state or federal government agency.

ANSWER:

14. Describe in detail Lisa Conigliaro Cadden's role at NECC in 2011 and 2012.

ANSWER:

VERIFICATION

STATE OF NEW JERSEY)
)
County of _____)

I, _____, after being duly sworn, hereby make oath that the foregoing answers to Interrogatories are true to the best of my knowledge, information, and belief.

_____

Sworn and subscribed before me this _____ day of _____, 2015.

_____
Notary Public

My commission expires on: _____.

REQUESTS FOR PRODUCTION

1. Produce all correspondence between you and any of the Premier Defendants, their employees, agents, or representatives.

RESPONSE:

2. Produce all correspondence and documents referring or related to the Premier Defendants' purchase of MPA from NECC in 2011 or 2012.

RESPONSE:

3. Produce all documents produced by the government to you during any civil, criminal, or administrative proceedings related to NECC's contaminated MPA.

RESPONSE:

4. Produce all policies, procedures, guidelines, instructions and training documents referring or relating to the compounding of MPA at the NECC facility.

RESPONSE:

5. Produce all documents referring or relating to NECC or Ameridose sending samples of insufficient size or volume to comply with USP 71 to ARL or any other testing laboratory.

RESPONSE:

6. Produce all documents referring or relating to any sterility, potency, endotoxin, or fungal testing that you received from ARL or any other laboratory related to MPA compounded by NECC or Ameridose in 2011 and 2012.

RESPONSE:

7. Produce all correspondence and documents referring or relating to fungal blooms or growth in or near NECC's cleanrooms.

RESPONSE:

8. Produce all documents referring or related to any complaints or communications with Liberty Industries regarding the design, manufacture, or installation of the cleanrooms at the NECC facility.

RESPONSE:

9. Produce all documents referring or relating to any complaints that NECC or Ameridose received related to the sterility or safety of their products, including but not limited to complaints by customers, current or former employees, or state or federal government agencies.

RESPONSE:

10. Produce all documents referring or relating to any complaints NECC or Ameridose received related to their compliance with state or federal laws or regulations, including but not limited to complaints by customers, current or former employees, or state or federal government agencies.

RESPONSE:

11. Produce all correspondence and documents referring or relating to NECC's response to the meningitis outbreak, including but not limited to, steps NECC took to prepare for any inspections of its facility.

RESPONSE:

12. Produce all training and instructional material for sales staff at NECC or MSM.

RESPONSE:

13. Produce copies of any and all New Jersey Pharmacy Licenses issued to NECC and/or Douglas Conigliaro, and all documents or communications between NECC and/or Douglas Conigliaro and the New Jersey Board of Pharmacy, including those referring or related to the procurement or renewal of said Licenses.

RESPONSE:

REQUESTS FOR ADMISION

1. Admit that, had any of the Premier Defendants asked for a copy of NECC's license in 2011, you would have provided a valid and up-to-date New Jersey pharmacy license.

ANSWER:

2. Admit that NECC represented to its customers, including the Premier Defendants, that it met or exceeded USP 797 standards.

ANSWER:

3. Admit that NECC represented to its customers, including the Premier Defendants, that its products, including MPA, were safe and sterile.

ANSWER:

4. Admit that the Massachusetts Board of Pharmacy ("Mass. BoP") inspected NECC on or about May 24, 2011.

ANSWER:

5. Admit that as a result of its inspection on or about May 24, 2011, the Mass. BoP issued an inspection report documenting its findings.

ANSWER:

6. Admit that NECC failed to submit a copy of the Mass. BoP's May 24, 2011 inspection report to the New Jersey Board of Pharmacy.

ANSWER:

7. Admit that NECC had a duty to its customers to ensure that its MPA was sterile prior to distributing it.

ANSWER:

Respectfully Submitted,

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Attorneys for the Premier Defendants

CERTIFICATE OF SERVICE

I hereby certify that on this 14th day of May, 2015, a true and accurate copy of the foregoing was served on Douglas Conigliaro by U.S. mail and on the other parties below electronically via the Court's CM/ECF system:

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Attorneys for the Saint Thomas Entities

/s/ Christopher Wolk
Christopher Wolk

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	MDL No. 2419 Dkt. No: 1:13-md-2419-RWZ
THIS DOCUMENT RELATES TO: Suits Naming the Premier Defendants	

THE PREMIER DEFENDANTS' FIRST INTERROGATORIES, REQUESTS FOR PRODUCTION OF DOCUMENTS, AND REQUESTS FOR ADMISSION PROPOUNDED TO GREGORY CONIGLIARO.

Come the Defendants, Premier Orthopaedic and Sports Medicine Associates of Southern New Jersey, LLC, trading as Premier Orthopaedic Associates; Premier Orthopaedic Associates Surgical Center, LLC; Kimberly Yvette Smith, M.D., a/k/a Kimberly Yvette Smith-Martin, M.D.; Thomas Dwyer, M.D.; Richard C. DiVerniero, M.D.; and Richard Strauss, M.D. (collectively, "Premier Defendants") , pursuant to Rules 26, 33, and 34 of the Federal Rules of Civil Procedure and the Local Rules for the District of Massachusetts, and propound the following Interrogatories, Requests for Production of Documents, and Requests for Admission to Gregory Conigliaro.

Each of the following Interrogatories shall be answered under oath, in writing, separately, to the fullest possible detail, and in accordance with the definitions and instructions set forth below. The answers shall be signed by the person making them, and a copy of the answers, together with objections, if any, shall be served within thirty (30) days after the service date of these interrogatories.

You are under a duty to seasonably supplement your response with respect to any Interrogatory directly addressed to the identity and location of persons having knowledge of discoverable matters. You are under a duty to amend a prior response if you obtain information on the basis of which you know that the response was incorrect when made, or that the response, though correctly made, is no longer true, and the circumstances are such that a failure to amend the response is, in substance, a knowing concealment.

DEFINITIONS

1. As used in this document, the terms "person(s)" and "individual(s)" mean any natural individual in any capacity whatsoever or any entity or organization, including divisions, departments, and other units therein, and shall include, but not be limited to, a public or private corporation, partnership, joint venture, voluntary or unincorporated association, organization, proprietorship, trust, estate, governmental agency, commission, bureau, or department.

2. As used in this document, the term "document" means any medium upon which intelligence or information can be recorded or retrieved, and includes without limitation, the original and each copy, regardless of origin and location, of any book, pamphlet, periodical, letter, memorandum (including any memorandum or report of a meeting or conversation), invoice, bill, order form, receipt, financial statement, accounting entry, diary, calendar, telex, telegram, cable, report, record, contract, agreement, study, handwritten note, draft, working paper, chart, paper, print, laboratory record, drawing or sketch, graph, index, lists, tape, photograph, microfilm, data sheet or data processing card, or any other written, recorded, transcribed, punched, taped, filmed, or graphic matter, however produced or reproduced, which is in your possession, custody, or control, or which was, but is no longer, in your possession, custody, or control.

3. As used in this document, the terms "identification," "identify," or "identity," when used in reference to a natural individual, require you to state his or her full name and residential and business address. Use of the term "document" in connection with the Interrogatories requires you to state the number of pages and the nature of the document, its title, its date, the name or names of its authors, and recipients, and its present location and custodian.

4. "You and "your" refers to Gregory Conigliaro and each of his present and former agents, representatives, and employees, attorneys and accountants, and each person acting or purporting to act on his behalf.

5. "Communication" means any oral or written utterance, notification, or statement of any nature whatsoever, by and to whomsoever made, including, but not limited to, correspondence, conversation, dialogue, discussions, interviews, consultants, and any other understanding between or among two or more persons.

INSTRUCTIONS

1. With respect to each Interrogatory, in addition to answering the question, you are to identify all documents that support, refer to, or evidence the subject matter of each Interrogatory and your answer thereto.

   If any or all identified documents are no longer in your possession, custody, or control because of destruction, loss, or any other reason, then you must do the following with respect to each and every document:

   A. Describe the nature of the document;

   B. State the date of the document;

   C. Identify the persons who sent and received the original and the copy of the document;

   D. State in as much detail as possible the contents of the documents; and

   E. State the manner and date of disposition of the document.

   If you contend that you are entitled to withhold from production any or all documents identified herein on the basis of attorney-client privilege, the work-product doctrine, or any other ground, then do the following with respect to each and every document:

   A. Describe the nature of the document;

   B. State the date of the document;

   C. Identify the persons who sent and received the original and a copy of the document;

   D. State the subject matter of the document; and

   E. State the basis upon which you contend you are entitled to withhold the document from production.

2. All documents produced should be organized and labeled to correspond to the specific Request in response to which they are being made available or should be produced as they are kept in the usual course of business.

3. The terms "and," "or," and "and/or" should be construed either disjunctively or conjunctively so as to bring within the scope of these Interrogatories and Requests any information that might otherwise be construed as outside their scope.

4. The term "any" should be construed to include the word "all," and "all" should be construed to include "any."

5. The present tense should be construed to include the past tense, and the past tense should be construed to include the present tense.

6. The singular should be construed to include the plural, and the plural should be construed to include the singular.

7. The terms "he" and "his" should be construed to include the words "she" and "her" or "hers," respectively and vice versa.

8. "Relating to," when referring to a document shall mean mentioning, describing, connected to or with, or discussing the stated subject matter.

INTERROGATORIES

1. Describe in detail your role at NECC and Ameridose, including job title, job description, and a description of your daily duties and activities in 2011 and 2012.

ANSWER:

2. Describe in detail the steps NECC took to compound, process, stopper, seal, package, and ship methylprednisolone acetate ("MPA") in 2011 and 2012, including but not limited to:

   a) The names of the individuals performing each step;

   b) The job titles for the individuals performing each step;

   c) The specific cleanroom or location in NECC's facility where each step took place;

   d) The tools, equipment, or machinery used for each step;

   e) Any changes to NECC's methods or procedures for compounding MPA, or the location where compounding MPA took place, that occurred in 2011 or 2012.

ANSWER:

3. Identify the total amount of MPA that NECC, and separately Ameriose, produced in each quarter of 2010, 2011, and 2012.

ANSWER:

4. Identify the types of vials and closures NECC used for MPA lots numbered 05212012@68, 06292012@26, and 08102012@51 (collectively "Contaminated Lots"), including whether the vials and enclosures were prewashed or presterilized, and identify their manufacturer(s).

ANSWER:

5. Identify any and all complaints that NECC and Ameridose received related to the sterility or safety of their products, including but not limited to complaints by customers, current and former employees, and state and federal government agencies.

ANSWER:

6. Identify any customers of NECC and Ameridose who performed site visits prior to placing orders with either company.

ANSWER:

7. Describe any policies, procedures, or protocols relating to or regarding customer site visits to the NECC facility, including the areas you allowed customers to inspect.

ANSWER:

8. Identify any customers who asked for information about prior recalls of NECC and Ameridose products prior to placing orders with either company.

ANSWER:

9. Identify and describe any information you gave customers about recalled NECC and Ameridose products in 2011 and 2012.

ANSWER:

10. Identify any and all complaints NECC or Ameridose received related to their compliance with state or federal laws and regulations, including but not limited to complaints by customers, current and former employees, and state and federal government agencies.

ANSWER:

11. Identify and describe any way in which NECC's cleanrooms were modified, altered, or expanded by NECC or Ameridose.

ANSWER:

12. Identify any policies, procedures, or guidelines in place at NECC in 2012 that encouraged employees to disclose mistakes in the compounding process, even if the mistakes necessitated destruction of product or halting production.

ANSWER:

13. Describe all disciplinary or enforcement action taken against NECC or Ameridose by any state or federal government agency.

ANSWER:

14. Describe in detail Lisa Conigliaro Cadden's role at NECC in 2011 and 2012.

ANSWER:

VERIFICATION

STATE OF NEW JERSEY)
)
County of _____)

I, _____, after being duly sworn, hereby make oath that the foregoing answers to Interrogatories are true to the best of my knowledge, information, and belief.

_____

Sworn and subscribed before me this _____ day of _____, 2015.

_____
Notary Public

My commission expires on: _____.

REQUESTS FOR PRODUCTION

1. Produce all correspondence between you and any of the Premier Defendants, their employees, agents, or representatives.

RESPONSE:

2. Produce all correspondence and documents referring or related to the Premier Defendants' purchase of MPA from NECC in 2011 or 2012.

RESPONSE:

3. Produce all documents produced by the government to you during any civil, criminal, or administrative proceedings related to NECC's contaminated MPA.

RESPONSE:

4. Produce all policies, procedures, guidelines, instructions and training documents referring or relating to the compounding of MPA at the NECC facility.

RESPONSE:

5. Produce all documents referring or relating to NECC or Ameridose sending samples of insufficient size or volume to comply with USP 71 to ARL or any other testing laboratory.

RESPONSE:

6. Produce all documents referring or relating to any sterility, potency, endotoxin, or fungal testing that you received from ARL or any other laboratory related to MPA compounded by NECC or Ameridose in 2011 and 2012.

RESPONSE:

7. Produce all correspondence and documents referring or relating to fungal blooms or growth in or near NECC's cleanrooms.

RESPONSE:

8. Produce all documents referring or related to any complaints or communications with Liberty Industries regarding the design, manufacture, or installation of the cleanrooms at the NECC facility.

RESPONSE:

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RESPONSE:

11. Produce all correspondence and documents referring or relating to NECC's response to the meningitis outbreak, including but not limited to, steps NECC took to prepare for any inspections of its facility.

RESPONSE:

12. Produce all training and instructional material for sales staff at NECC or MSM.

RESPONSE:

13. Produce copies of any and all New Jersey Pharmacy Licenses issued to NECC and/or Gregory Conigliaro, and all documents or communications between NECC and/or Gregory Conigliaro and the New Jersey Board of Pharmacy, including those referring or related to the procurement or renewal of said Licenses.

RESPONSE:

REQUESTS FOR ADMISION

1. Admit that, had any of the Premier Defendants asked for a copy of NECC's license in 2011, you would have provided a valid and up-to-date New Jersey pharmacy license.

ANSWER:

2. Admit that NECC represented to its customers, including the Premier Defendants, that it met or exceeded USP 797 standards.

ANSWER:

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ANSWER:

4. Admit that the Massachusetts Board of Pharmacy ("Mass. BoP") inspected NECC on or about May 24, 2011.

ANSWER:

5. Admit that as a result of its inspection on or about May 24, 2011, the Mass. BoP issued an inspection report documenting its findings.

ANSWER:

6. Admit that NECC failed to submit a copy of the Mass. BoP's May 24, 2011 inspection report to the New Jersey Board of Pharmacy.

ANSWER:

7. Admit that NECC had a duty to its customers to ensure that its MPA was sterile prior to distributing it.

ANSWER:

Respectfully Submitted,

BLUMBERG & WOLK, LLC

/s/ Christopher Wolk
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Attorneys for the Premier Defendants

CERTIFICATE OF SERVICE

I hereby certify that on this 14th day of May, 2015, a true and accurate copy of the foregoing was served on Gregory Conigliaro by U.S. mail and on the other parties below electronically via the Court's CM/ECF system:

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Attorneys for the Saint Thomas Entities

/s/ Christopher Wolk
Christopher Wolk

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	MDL No. 2419 Dkt. No: 1:13-md-2419-RWZ
THIS DOCUMENT RELATES TO: Suits Naming the Premier Defendants	

THE PREMIER DEFENDANTS' FIRST INTERROGATORIES, REQUESTS FOR PRODUCTION OF DOCUMENTS, AND REQUESTS FOR ADMISSION PROPOUNDED TO BARRY CADDEN.

Come the Defendants, Premier Orthopaedic and Sports Medicine Associates of Southern New Jersey, LLC, trading as Premier Orthopaedic Associates; Premier Orthopaedic Associates Surgical Center, LLC; Kimberly Yvette Smith, M.D., a/k/a Kimberly Yvette Smith-Martin, M.D.; Thomas Dwyer, M.D.; Richard C. DiVerniero, M.D.; and Richard Strauss, M.D. (collectively, "Premier Defendants") , pursuant to Rules 26, 33, and 34 of the Federal Rules of Civil Procedure and the Local Rules for the District of Massachusetts, and propound the following Interrogatories, Requests for Production of Documents, and Requests for Admission to Barry Cadden.

Each of the following Interrogatories shall be answered under oath, in writing, separately, to the fullest possible detail, and in accordance with the definitions and instructions set forth below. The answers shall be signed by the person making them, and a copy of the answers, together with objections, if any, shall be served within thirty (30) days after the service date of these interrogatories.

You are under a duty to seasonably supplement your response with respect to any Interrogatory directly addressed to the identity and location of persons having knowledge of discoverable matters. You are under a duty to amend a prior response if you obtain information on the basis of which you know that the response was incorrect when made, or that the response, though correctly made, is no longer true, and the circumstances are such that a failure to amend the response is, in substance, a knowing concealment.

DEFINITIONS

1. As used in this document, the terms "person(s)" and "individual(s)" mean any natural individual in any capacity whatsoever or any entity or organization, including divisions, departments, and other units therein, and shall include, but not be limited to, a public or private corporation, partnership, joint venture, voluntary or unincorporated association, organization, proprietorship, trust, estate, governmental agency, commission, bureau, or department.

2. As used in this document, the term "document" means any medium upon which intelligence or information can be recorded or retrieved, and includes without limitation, the original and each copy, regardless of origin and location, of any book, pamphlet, periodical, letter, memorandum (including any memorandum or report of a meeting or conversation), invoice, bill, order form, receipt, financial statement, accounting entry, diary, calendar, telex, telegram, cable, report, record, contract, agreement, study, handwritten note, draft, working paper, chart, paper, print, laboratory record, drawing or sketch, graph, index, lists, tape, photograph, microfilm, data sheet or data processing card, or any other written, recorded, transcribed, punched, taped, filmed, or graphic matter, however produced or reproduced, which is in your possession, custody, or control, or which was, but is no longer, in your possession, custody, or control.

3. As used in this document, the terms "identification," "identify," or "identity," when used in reference to a natural individual, require you to state his or her full name and residential and business address. Use of the term "document" in connection with the Interrogatories requires you to state the number of pages and the nature of the document, its title, its date, the name or names of its authors, and recipients, and its present location and custodian.

4. "You and "your" refers to Barry Cadden and each of his present and former agents, representatives, and employees, attorneys and accountants, and each person acting or purporting to act on his behalf.

5. "Communication" means any oral or written utterance, notification, or statement of any nature whatsoever, by and to whomsoever made, including, but not limited to, correspondence, conversation, dialogue, discussions, interviews, consultants, and any other understanding between or among two or more persons.

INSTRUCTIONS

1. With respect to each Interrogatory, in addition to answering the question, you are to identify all documents that support, refer to, or evidence the subject matter of each Interrogatory and your answer thereto.

   If any or all identified documents are no longer in your possession, custody, or control because of destruction, loss, or any other reason, then you must do the following with respect to each and every document:

   A. Describe the nature of the document;

   B. State the date of the document;

   C. Identify the persons who sent and received the original and the copy of the document;

   D. State in as much detail as possible the contents of the documents; and

   E. State the manner and date of disposition of the document.

   If you contend that you are entitled to withhold from production any or all documents identified herein on the basis of attorney-client privilege, the work-product doctrine, or any other ground, then do the following with respect to each and every document:

   A. Describe the nature of the document;

   B. State the date of the document;

   C. Identify the persons who sent and received the original and a copy of the document;

   D. State the subject matter of the document; and

   E. State the basis upon which you contend you are entitled to withhold the document from production.

2. All documents produced should be organized and labeled to correspond to the specific Request in response to which they are being made available or should be produced as they are kept in the usual course of business.

3. The terms "and," "or," and "and/or" should be construed either disjunctively or conjunctively so as to bring within the scope of these Interrogatories and Requests any information that might otherwise be construed as outside their scope.

4. The term "any" should be construed to include the word "all," and "all" should be construed to include "any."

5. The present tense should be construed to include the past tense, and the past tense should be construed to include the present tense.

6. The singular should be construed to include the plural, and the plural should be construed to include the singular.

7. The terms "he" and "his" should be construed to include the words "she" and "her" or "hers," respectively and vice versa.

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INTERROGATORIES

1. Describe in detail your role at NECC and Ameridose, including job title, job description, and a description of your daily duties and activities in 2011 and 2012.

ANSWER:

2. Describe in detail the steps NECC took to compound, process, stopper, seal, package, and ship methylprednisolone acetate ("MPA") in 2011 and 2012, including but not limited to:

   a) The names and job titles of the individuals performing each step;

   b) The specific cleanroom or location in NECC's facility where each step took place;

   c) The tools, equipment, or machinery used for each step;

   d) Any changes to NECC's methods or procedures for compounding MPA, or the location where compounding MPA took place, that occurred in 2011 or 2012.

ANSWER:

3. Identify the total amount of MPA that NECC, and separately Ameriose, produced in each quarter of 2010, 2011, and 2012.

ANSWER:

4. Identify the types of vials and closures NECC used for MPA lots numbered 05212012@68, 06292012@26, and 08102012@51 (collectively "Contaminated Lots"), including whether the vials and enclosures were prewashed or presterilized, and identify their manufacturer(s) and from whom they were purchased by NECC.

ANSWER:

5. Identify any and all complaints that NECC and Ameridose received related to the sterility or safety of their products, including but not limited to complaints by customers, current and former employees, and state and federal government agencies.

ANSWER:

6. Identify any customers of NECC and Ameridose who performed site visits prior to placing orders with either company.

ANSWER:

7. Describe any policies, procedures, or protocols relating to or regarding customer site visits to the NECC facility, including the areas you allowed customers to inspect.

ANSWER:

8. Identify any customers who took the following actions prior to placing orders with NECC or Ameridose:

   a. Verified whether NECC's quality processes demonstrated that NECC was a reputable and safe supplier of sterile injectable compounds;

   b. Determined if NECC was an accredited compounding pharmacy;

   c. At least once annually, unannounced, visited NECCs corporate offices and compounding facilities and conferred with NECC's corporate, pharmacy, and compounding staff;

   d. Determined whether NECC had any product liability lawsuits filed against it for preparations compounded;

   e. Determined whether there had ever been recalls of any of NECC's compounded preparations;

   f. Evaluated NECC's standard operating procedures and manuals;

   g. Evaluated NECC's pharmacist technician training;

   h. Evaluated NECC's policies and procedures for sterility testing;

   i. Evaluated examples of batch reports for product being considered for outsourcing;

   j. Evaluated examples of quality-control reports;

   k. Obtained and evaluated history of the results of all NECC accreditation or regulatory surveys conducted of NECC's sites, including copies of significant regulatory actions;

   l. Determined if NECC could provide documentation of the end-product testing processes used to determine that compounded sterile preparations are sterile and free of pyrogens and unintended particulate matter;

   m. Evaluated whether NECC could assure that each compounded sterile preparation was sterile and free of pyrogens and unintended particulate matter according to professional established and accepted quality monitoring data;

   n. Determined whether NECC performed nonviable and viable particle testing in primary engineering controls (e.g., laminar flow workbench, biological safety cabinet) and room air according to USP chapter 797 standards;

o. Determined whether NECC performed routine surface microbiological and fungal environmental monitoring to minimize contamination;

p. Determined whether NECC had a policy that required validation of new or changed facilities, equipment, processes, or container types, for sterility and repeatability;

q. Determined whether NECC met ASHP, NIOSH and USP chapter 797 guidelines for the handling of hazardous agents;

r. Evaluated NECC's quality management program, specifically as it relates to facility cleaning and validation, staff training, and competency assessment;

s. Evaluated NECC's risk assessment program to ensure that medication errors are not introduced by new or increased outsourced compounding activities; or

t. Determined whether NECC had a history of disciplinary or punitive actions by any regulatory agency.

ANSWER:

9. Describe any information you, NECC, or Ameridose provided to each customer in response to the inquiries identified in the previous Interrogatory.

ANSWER:

10. Identify any and all complaints NECC or Ameridose received related to their compliance with state or federal laws and regulations, including but not limited to complaints by customers, current and former employees, and state and federal government agencies.

ANSWER:

11. Identify and describe any way in which NECC's cleanrooms were modified, altered, or expanded by NECC or Ameridose.

ANSWER:

12. Identify any policies, procedures, or guidelines in place at NECC in 2012 that encouraged employees to disclose mistakes in the compounding process, even if the mistakes necessitated destruction of product or halting production.

ANSWER:

13. Describe all disciplinary or enforcement action taken against NECC or Ameridose by any state or federal government agency.

ANSWER:

14. Describe in detail Lisa Conigliaro Cadden's role at NECC in 2011 and 2012.

ANSWER:

VERIFICATION

STATE OF NEW JERSEY)
)
County of _____)

I, _____, after being duly sworn, hereby make oath that the foregoing answers to Interrogatories are true to the best of my knowledge, information, and belief.

_____

Sworn and subscribed before me this _____ day of _____, 2015.

_____
Notary Public

My commission expires on: _____.

REQUESTS FOR PRODUCTION

1. Produce all correspondence between you and any of the Premier Defendants, their employees, agents, or representatives.

RESPONSE:

2. Produce all correspondence and documents referring or related to the Premier Defendants' purchase of MPA from NECC in 2011 or 2012.

RESPONSE:

3. Produce all documents produced by the government to you during any civil, criminal, or administrative proceedings related to NECC's contaminated MPA.

RESPONSE:

4. Produce all policies, procedures, guidelines, instructions and training documents referring or relating to the compounding of MPA at the NECC facility.

RESPONSE:

5. Produce all documents referring or relating to NECC or Ameridose sending sufficient samples, by size or volume, to comply with USP 71 to ARL or any other testing laboratory.

RESPONSE:

6. Produce all correspondence and documents referring or relating to fungal blooms or growth in or near NECC's cleanrooms.

RESPONSE:

7. Produce all documents referring or relating to any complaints that NECC or Ameridose received related to the sterility or safety of their products, including but not limited to complaints by customers, current or former employees, or state or federal government agencies.

RESPONSE:

8. Produce all documents referring or relating to any complaints NECC or Ameridose received related to their compliance with state or federal laws or regulations, including but not limited to complaints by customers, current or former employees, or state or federal government agencies.

RESPONSE:

9. Produce all correspondence and documents referring or relating to NECC's response to the meningitis outbreak, including but not limited to, steps NECC took to prepare for any inspections of its facility.

RESPONSE:

10. Produce all training and instructional material for sales staff at NECC or MSM.

RESPONSE:

11. Produce copies of any and all New Jersey Pharmacy Licenses issued to NECC and/or Barry Cadden, and all documents or communications between NECC and/or Barry Cadden and the New Jersey Board of Pharmacy, including those referring or related to the procurement or renewal of said Licenses.

RESPONSE:

REQUESTS FOR ADMISION

1. Admit that you were NECC's pharmacist in charge in 2011 and 2012.

ANSWER:

2. Admit that you signed NECC's application for a pharmacy license in New Jersey representing yourself to be NECC's pharmacist in charge.

ANSWER:

3. Admit that the New Jersey Board of Pharmacy granted you a pharmacist license number, permitting you to practice as a pharmacist in the state of New Jersey.

ANSWER:

4. Admit that on or about October 12, 2012, NECC executed a Voluntary Surrender Agreement in which it voluntarily surrendered its license to practice pharmacy in the state of New Jersey.

ANSWER:

5. Admit that on or about October 20, 2012, you executed a Voluntary Surrender Agreement in which you voluntarily surrendered your license to practice as a pharmacist in the state of New Jersey.

ANSWER:

6. Admit that as the pharmacist in charge at NECC, you had the authority and responsibility for compliance with the laws and rules pertaining to the practice of pharmacy of NECC at its practice site.

ANSWER:

7. Admit that, had any of the Premier Defendants asked for a copy of NECC's license in 2011, you would have provided a valid and up-to-date New Jersey pharmacy license.

ANSWER:

8. Admit that NECC represented to potential customers, including the Premier Defendants, that it met or exceeded USP 797 standards.

ANSWER:

9. Admit that NECC represented to potential customers, including the Premier Defendants, that its products, including MPA, were safe and sterile.

ANSWER:

10. Admit that the Massachusetts Board of Pharmacy ("Mass. BoP") inspected NECC on or about May 24, 2011.

ANSWER:

11. Admit that as a result of its inspection on or about May 24, 2011, the Mass. BoP issued an inspection report documenting its findings.

ANSWER:

12. Admit that you did not submit a copy of the Mass. BoP's May 24, 2011 inspection report to the New Jersey Board of Pharmacy.

ANSWER:

13. Admit that you owed a duty to the Plaintiffs to ensure that NECC's MPA was sterile prior to distributing it to customers.

ANSWER:

14. Admit that the documents attached as Exhibit B are NECC's Logged Formula Worksheets for the MPA lots numbered 05212012@68, 06292012@26, and 08102012@51 (collectively "Contaminated Lots").

ANSWER:

15. Admit that in each Logged Formula Worksheet in Exhibit B, the pharmacist referred to as "GC" is Glenn Chin.

ANSWER:

16. Admit that the Logged Formula Worksheet for lot 06292012@26, attached as Exhibit B, states that the MPA was autoclaved for twenty (20) minutes at 121 C. and 15 PSI.

ANSWER:

17. Admit that NECC's Standard Operating Procedures required that the MPA be autoclaved for fifteen (15) minutes at 121 C. and 15 PSI.

ANSWER:

18. Admit that the Logged Formula Worksheets in Exhibit B state that Joseph P. Connolly was the technician for MPA lots 05212012@68 and 06292012@26.

ANSWER:

19. Admit that Glenn Chin compounded lot 08102012@51.

ANSWER:

20. Admit that Glenn Chin and Joseph Connolly compounded lots 05212012@68 and 06292012@26.

ANSWER:

21. Admit that NECC violated its own standard operating procedures by allowing Joseph Connolly (a technician) to compound two of the three contaminated lots.

ANSWER:

22. Admit that Exhibit C is NECC's General Overview of Policies and Procedures for Compounding Sterile Products.

ANSWER:

23. Admit that Exhibit C states, in part:

C. Personnel

a. All sterile compounding is performed by properly trained and validated pharmacists (*no* technicians).

ANSWER:

24. Admit that the documents attached as Exhibit D are reports from Analytical Research Laboratories ("ARL") related to the sterility and endotoxin testing ARL performed on NECC's MPA from the Contaminated Lots.

ANSWER:

25. Admit that NECC submitted only two 5 mL vials of MPA from each of the Contaminated Lots to ARL for testing.

ANSWER:

26. Admit that USP standards for sterility testing required a larger sample size than two 5 mL vials per lot of MPA.

ANSWER:

27. Admit that USP 797 requires an ISO 5 space for stoppering vials of MPA.

ANSWER:

28. Admit that NECC stoppered the Contaminated Lots in an ISO 7 space.

ANSWER:

29. Admit that the documents attached as Exhibit E are true and accurate copies of emails you sent to Glenn Chinn in the normal course of NECC's business.

ANSWER:

30. Admit that in the email you sent Glenn Chin on Wednesday, August 10, attached as Exhibit E, you stated, "I am told that the lots for some drugs almost never coincide with the available test data."

ANSWER:

31. Admit that in the email you sent Glenn Chin on Wednesday, August 10, attached as Exhibit E, you stated, "I was told that we are only testing rarely and dispensing many untested lots."

ANSWER:

32. Admit that Exhibit F is a true and accurate copy of an email you received from Glenn Chinn on Monday, December 19, 2011.

ANSWER:

33. Admit that the email in Exhibit F was sent in the normal course of NECC's business.

ANSWER:

34. Admit that in the email attached as Exhibit F, Glenn Chin indicated that he was using "MTX" that had expired in 2007 in NECC's injectable products in 2011.

ANSWER:

Respectfully Submitted,

BLUMBERG & WOLK, LLC

/s/ Christopher Wolk

Jay Blumberg
Christopher Wolk
158 Delaware Street
P.O. Box 68
Woodbury, NJ 08096
(856) 848-7472

Attorneys for the Premier Defendants

CERTIFICATE OF SERVICE

I hereby certify that on this 14th day of May, 2015, a true and accurate copy of the foregoing was served on Barry Cadden by U.S. mail and on the other parties below electronically via the Court's CM/ECF system:

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/s/ Christopher Wolk
Christopher Wolk

EXHIBIT B

Logged Formula Worksheet (standard)

5/21/2012 9:58:08 AM
Page 1

NEW ENGLAND COMPOUNI
697 WAVERLY ST.
697 WAVERLY ST.
FRAMINGHAM, MA 01702 Ph

METHYLPRED. AC (PF) 80MG/ML INJECTABLE

Flavor:
Description:
Schedule: L

Quantity made: 12500 ML
Batch yield: 12,500.000
Qty remaining: 12,500.000
PCCA ID:
Route of admin:

Log ID: 2299381

Date made: 5/21/2012
Lot number: 05212012@68
Beyond use date: November 17, 2012 9:57 AM
180 days after compounding date
Pharmacist: GC
Technician: JOSEPH P CONNOLLY
NDC1:
Packaging:
Equipment:

Pricing calculations fr
Estimated price $9.
Ingredient cost $0.
Device cost $0.
Time cost $0.
Profit

Labeling: SHAKE WELL***SDV***
Stability information:

	Chemicals	Sch.	Quantity used	QS	
1	METHYLPREDNISOLONE ACETATE USP (STERILE) PI Lot #: 78740/A Chemical Code: Balance: 8113/A	-	1000 GM Exp. date: 4/30/2016 Mfg: Volume: Medisca Potency: QS amount: NDC: 49452-4668-02	☑	
2	POLYETHYLENE GLYCOL 3350 NF (STERILE) BASE Lot #: 77089/A Chemical Code: Balance:	-	352.5 GM Exp. date: 2/28/2014 Mfg: MEDISCA Volume: Potency: QS amount: NDC:	☐	Whslr: MEDISCA $7,755.00 07/21/2005 AWP: $0.00 Each ML contains 0.0282 GM or 2.82% ChemInvID: 0
3	SODIUM CHLORIDE (STERILE) GRANUALE Lot #: 11020203 Chemical Code: Balance:	-	28.5 GM Exp. date: 11/10/2013 Mfg: MEDISCA Volume: Potency: QS amount: NDC: 51927108700	☐	Whslr: MEDISCA $0.56 04/02/2012 AWP: $5.13 Each ML contains 0.00228 GM or 0.228% ChemInvID: 0
4	WATER FOR INJECTION INJ Lot #: J2B670 Chemical Code: Balance:		12500 ML Exp. date: 8/31/2014 Mfg: BRAUN Volume: Potency: QS amount: NDC: 00409488798	☒	Whslr: BRAUN $25,000.00 06/17/2005 AWP: $61.13 Each ML contains 1 ML or 100% ChemInvID: 300
5	POLYSORBATE 80 (STERILE) LIQUID Lot #: 79814/C Chemical Code: Balance:	O	47.5 ML Exp. date: 8/31/2013 Mfg: MEDISCA Volume: Potency: QS amount: NDC:	☐	Whslr: MEDISCA $0.00 04/02/2009 AWP: $0.00 Each ML contains 0.0038 ML or 0.38% ChemInvID: 170
6	SODIUM PHOSPHATE MONOBASIC (STERILE) POWDI Lot #: 11010925 Chemical Code: Balance:	-	82.375 GM Exp. date: 8/11/2013 Mfg: LETCO Volume: Potency: QS amount: NDC:	☐	Whslr: PROFESSIONAL COMPOUN $82.38 09/30/2008 AWP: $0.00 Each ML contains 0.00659 GM or 0.659% ChemInvID: 0
7	SODIUM PHOSPHATE DIBASIC (STERILE) POWDER Lot #: 6140892 Chemical Code: Balance: K32703		17.125 GM Exp. date: 8/1/2012 Mfg: PCCA Volume: JT Baker Potency: QS amount: NDC:	☐	Whslr: PROFESSIONAL COMPOUN $0.00 11/01/2011 AWP: $0.00 Each ML contains 0.00137 GM or 0.137% ChemInvID: 289

(Added all GM & GMS: 1,480.50) $32,837.94

Log Instructions & Notes

Originally made as: 12500 METHYLPRED. AC (PF) 80MG/ML INJECTABLE
Calculated lot number: 05212012@68 Beyond use date: 11/17/2012
FORMULA INSTRUCTIONS:

ZEBRA BAR CODES:
99600010504 - 1mL VIAL
99600020504 - 2mL VIAL
99600050504 - 5mL VIAL

Date entered: 5/21/2012 9:57:45 AM Last modified: 5/21/2012 9:58:06 AM by: LAB
Checked by: _____ Date: 05/21/12

MODEL No. MLS-3381

OPERATION DATE 2012/05/21
TIME PM 08:45:12

COURSE 1

CYCLE STARTED

TIME ELAPSED	TEMP CENT.	PRESS kPa	STATUS CYCLE
00:11:58	090.0	14	HEAT
00:13:59	100.0	24	HEAT
00:22:01	106.4	30	HEAT
00:25:25	121.0	104	STERI.
00:27:25	121.8	110	STERI.
00:29:25	121.6	111	STERI.
00:31:25	121.6	109	STERI.
00:33:25	121.7	111	STERI.
00:35:25	121.7	111	STERI.
00:37:25	121.6	110	STERI.
00:39:25	121.7	112	STERI.
00:40:29	121.7	112	COOL
01:14:15	064.9	5	COMPLETE

START TIME PM 08:45:12
END TIME PM 09:59:27

Logged Formula Worksheet (standard)

6/29/2012 9:06:36 AM
Page 1

LG235696

NEW ENGLAND COMPOUND
697 WAVERLY ST.
697 WAVERLY ST.
FRAMINGHAM, MA 01702 P

N + 352.504 g
N + 28.506 g
N + 82.375 g
N + 17.125 g

BF 06-29-2012

Formula ID: 2228
Log ID: 235896

METHYLPRED. AC (PF) 80MG/ML INJECTABLE

Flavor:
Description:
Schedule: L

Quantity made: 12500 ML
Batch yield: 12,500.000
Qty remaining: 12,500.000
PCCA ID:
Route of admin:

Pricing calculations from t
Estimated price $9.00 as
Ingredient cost $0.00
Device cost $0.00
Time cost
Profit

Date made: 6/29/2012
Lot number: 06292012@26
Beyond use date: December 26, 2012 9:06 AM
180 days after compounding date
Pharmacist: GC
Technician: <NONE>
NDC1:
Packaging:
Equipment:

15L

SB
06-27-12 A11:41 OUT

Labeling: SHAKE WELL***SDV***
Stability information:

NECC

Teflon
05-24-12 P03:42 OUT
Home outlet closed 2N

	Chemicals	Sch.	Quantity used	QS (B		
1	METHYLPREDNISOLONE ACETATE USP (STERILE) P Lot #: ~~78740/A~~ Chemical Code: Balance: 3287218	-	2x500gm = 1000 GM Exp. date: ~~4/30/2016~~ Mfg: Medisca Volume: Potency: QS amount: 01-30-17 NDC: 49452-4688-02	☐	Whls	
2	POLYETHYLENE GLYCOL 3350 NF (STERILE) BASE Lot #: 77089/A Chemical Code: Balance:	-	352.5 GM Exp. date: 2/28/2014 Mfg: MEDISCA Volume: Potency: QS amount: NDC:	☐	$7,755.00 Whlsr: MEDISCA AWP: Each ML contains 0.0282 GM or 2.82% CheminvID: 0	07/21/2005 $0.00
3	SODIUM CHLORIDE (STERILE) GRANUALE Lot #: 11020203 Chemical Code: Balance:	-	28.5 GM Exp. date: 11/10/2013 Mfg: MEDISCA Volume: Potency: QS amount: NDC: 61927108700	☐	$0.56 Whlsr: MEDISCA AWP: Each ML contains 0.00228 GM or 0.228% CheminvID: 0	04/02/2012 $5.13
4	WATER FOR INJECTION INJ Lot #: J2A488 Chemical Code: Balance:		12500 ML Exp. date: 7/31/2014 Mfg: BRAUN Volume: Potency: QS amount: NDC: 00409488799	☒	$25,000.00 Whlsr: BRAUN AWP: Each ML contains 1 ML or 100% CheminvID: 300	06/17/2005 $61.13
5	POLYSORBATE 80 (STERILE) LIQUID Lot #: 79814/C Chemical Code: Balance:	O	47.5 ML Exp. date: 8/31/2013 Mfg: MEDISCA Volume: Potency: QS amount: NDC:	☐	$0.00 Whlsr: MEDISCA AWP: Each ML contains 0.0038 ML or 0.38% CheminvID: 170	04/02/2009 $0.00 (done)
6	SODIUM PHOSPHATE MONOBASIC (STERILE) POWDI Lot #: 11010925 Chemical Code: Balance:	-	82.375 GM Exp. date: 8/11/2013 Mfg: LETCO Volume: Potency: QS amount: NDC:	☐	$82.38 Whlsr: PROFESSIONAL COMPOUN AWP: Each ML contains 0.00659 GM or 0.659% CheminvID: 0	09/30/2008 $0.00
7	SODIUM PHOSPHATE DIBASIC (STERILE) POWDER Lot #: ~~C140892~~ Chemical Code: Balance: K32473		17.125 GM Exp. date: ~~8/1/2013~~ Mfg: PCCA Volume: 5.To QS amount: 5-31-2013 BAYER NDC:	☐	$0.00 Whlsr: PROFESSIONAL COMPOUN AWP: Each ML contains 0.00137 GM or 0.137% CheminvID: 289	11/01/2011 $0.00

(Added all GM & GMS: 1,480.50) $32,837.94

Log Instructions & Notes

11 Vials
Lot# - 1070553
Exp - Apr'17

Originally made as: 12500 METHYLPRED. AC (PF) 80MG/ML INJECTABLE
Calculated lot number: 06292012@26 Beyond use date: 12/26/2012
FORMULA INSTRUCTIONS:

ZEBRA BAR CODES:
99600010504 - 1mL VIAL
99600020504 - 2mL VIAL
99600050504 - 5mL VIAL

pH = 5 on paper 325 (2) MT = 60'

Date entered: 6/29/2012 9:06:22 AM Last modified: 6/29/2012 9:06:34 AM by: LAB
Checked by: Date: 6/29/12

BASE Beaker

NECC

06-22-12 P03:05 OUT

BASE S_0 B_0

MODEL No. MLS-3781

OPERATION DATE 2012/06/30
TIME PM 08:01:18

COURSE 1

CYCLE STARTED

TIME ELAPSED	TEMP CENT.	PRESS kPa	STATUS CYCLE
00:09:53	090.0	6	HEAT
00:13:28	100.0	23	HEAT
00:21:30	101.5	10	HEAT
00:25:41	121.0	104	STERI.
00:27:41	121.8	110	STERI.
00:29:41	121.8	110	STERI.
00:31:41	121.8	110	STERI.
00:33:41	121.6	110	STERI.
00:35:41	121.8	112	STERI.
00:37:41	121.7	112	STERI.
00:39:41	121.6	111	STERI.
00:40:46	121.8	114	COOL
01:15:00	064.9	4	COMPLETE

START TIME PM 08:01:18
END TIME PM 09:16:18

Logged Formula Worksheet (standard)
6/29/2012 9:06:36 AM
Page 2

L6235896

NEW ENGLAND COMPOUNDING CTR
697 WAVERLY ST.
697 WAVERLY ST.
FRAMINGHAM, MA 01702 Ph. 800-994-6322

METHYLPRED. AC (PF) 80MG/ML INJECTABLE

Flavor:
Description:

Schedule: L

Active ☑
Formula ID: 2228
Log ID: 235896

Quantity made: 12500 ML

Batch yield: 12,500.000
Qty remaining: 12,500.000

PCCA ID:
Route of admin:

12/09/09 POLYSORBATE-80 DOUBLED FROM 0.194ML/100ML TO 0.38ML/100ML GC

MATERIALS: STERILE BEAKER, STERILE SPIN BAR, STERILE HOMOGENIZER ELEMENT
medisca 500gm plastic bottle weighs 98gms, plastic seal ring weighs 0.7gms
medisca 1kg plastic bottle weighs 145gms, WITH TOP
1) WEIGH CHEMICALS IN STERILE WEIGH CUPS ON ELECTRONIC ANALYTICAL BALANCE
2) IN HOOD DISSOLVE BASE-B, SODIUM PHOSPHATE MONOBASIC, SODIUM PHOSPHATE DIBASIC, SODIUM CHLORIDE, AND POLYSORBATE -80 IN VORTEX OF 80% FINAL VOLUME OF STERILE WATER.FILTER SOLUTION THROUGH A 0.22MICRON NALGENE FILTER.
3) SLOWLY ADD METHYLPREDNISOLONE ACETATE TO VORTEX OF ABOVE SOLUTION.
4) HOMOGENIZE AT HIGH SPEED FOR 2-5 MINUTES (VOLUME DEP.)
5) QS TO FINAL VOLUME WITH STERILE WATER FOR INJECTION.
6) COVER WITH MULTIPLE LAYERS OF FOIL AND SEAL WITH AUTOCLAVE INDICATOR TAPE
7) AUTOCLAVE AT 121C-15PSI-20MIN
####SPRAY EXTERIOR OF SEALED BEAKER WITH 70% IPA#####
8) RETURN TO HOOD AND REHOMOGENIZE. CREATE VORTEX AND ALLOW TO SOIN TILL COOLED TO ROOM TEMP.
9) FILL STERILE AMBER VIALS USING BAXA REPEATER PUMP VIA DISPOSABLE STERILE TUBING
10) CAP ,CRIMP, AND LABEL

####PULL RANDOM VIALS FOR APPROPRIATE ANALYSIS#####

Date entered: 6/29/2012 9:06:22 AM Last modified: 6/29/2012 9:06:34 AM by: LAB
Checked by: _____ Date: ____/____/_____

Logged Formula Worksheet (standard)
8/10/2012 2:43:06 PM
Page 1

NEW ENGLAND COMPOUN
697 WAVERLY ST.
697 WAVERLY ST.
FRAMINGHAM, MA 01702

N + 352.506 g
N + 28.501 g
N + 82.377 g
N + 17.129 g

METHYLPRED. AC (PF) 80MG/ML INJECTABLE

08-10-2012

Flavor:
Description:
Schedule: L
Active ☑
Formula ID: 2228

Quantity made: 12500 ML
Batch yield: 12,500.000
Qty remaining: 12,500.000
PCCA ID:
Route of admin:

Date made: 8/10/2012
Lot number: 08102012@51
Beyond use date: February 6, 2013 2:42 PM
180 days after compounding date
Pharmacist: GC
Technician: JOSEPH P CONNOLLY
NDC1:
Packaging:
Equipment:

Pricing calculations from the l	
Estimated price	$9.00 as of
Ingredient cost	$0.00
Device cost	$0
Time cost	$0
Profit	$9

08-07-12 A11:42 OUT

Labeling: SHAKE WELL***SDV***
Stability information:

Chemicals	Sch.	Quantity used	QS (Balance)		
1 METHYLPREDNISOLONE ACETATE USP (STERILE) PI - 2 x 500 gm = Lot #: ~~78740/A~~ Mfg: Chemical Code: Volume: Potency: Balance: 81113/6 + 80494/8 Medisca		1000 GM Exp. date: ~~4/30/2016~~ 09-30-16 QS amount: 09-30-16 NDC: 49452-4688-02	☐	Whlsr: Each	
POLYETHYLENE GLYCOL 3350 NF (STERILE) BASE Lot #: 76985/A Mfg: MEDISCA Chemical Code: Volume: Potency: Balance:		352.5 GM Exp. date: 8/31/2013 QS amount: NDC:	☐	Whlsr: Each	ChemInvID: 0
SODIUM CHLORIDE (STERILE) GRANUALE Lot #: 11020203 Mfg: MEDISCA Chemical Code: Volume: Potency: Balance:		28.5 GM Exp. date: 11/10/2013 QS amount: NDC: 51927108700	☐	$0.56 4/2/2012 Whlsr: MEDISCA AWP: $5.13 Each ML contains 0.00228 GM or 0.228%	ChemInvID: 0
WATER FOR INJECTION INJ Lot #: J2B670 Mfg: BRAUN Chemical Code: Volume: Potency: Balance:		12500 ML Exp. date: 8/31/2014 QS amount: NDC: 00409488799	☒	$25,000.00 6/17/2005 Whlsr: BRAUN AWP: $61.13 Each ML contains 1 ML or 100%	ChemInvID: 300
5 POLYSORBATE 80 (STERILE) LIQUID Lot #: 79814/C Mfg: MEDISCA Chemical Code: Volume: Potency: Balance:	O	47.5 ML Exp. date: 8/31/2013 QS amount: NDC:	☐	$0.00 4/2/2009 Whlsr: MEDISCA AWP: $0.00 Each ML contains 0.0038 ML or 0.38%	ChemInvID: 170
SODIUM PHOSPHATE MONOBASIC (STERILE) POWDER Lot #: 11010925 Mfg: LETCO Chemical Code: Volume: Potency: Balance:		82.375 GM Exp. date: 8/11/2013 QS amount: NDC:	☐	$82.38 9/30/2008 Whlsr: PROFESSIONAL COMPOUN AWP: $0.00 Each ML contains 0.00659 GM or 0.659%	ChemInvID: 0
SODIUM PHOSPHATE DIBASIC (STERILE) POWDER Lot #: ~~G140892~~ Mfg: ~~PCCA~~ JT Baker Chemical Code: Volume: Potency: Balance: K39H09		17.125 GM Exp. date: ~~8/1/2013~~ QS amount: 08-31-2013 NDC:	☐	$0.00 11/1/2011 Whlsr: PROFESSIONAL COMPOUN AWP: $0.00 Each ML contains 0.00137 GM or 0.137%	ChemInvID: 269
		(Added all GM & GMS: 1,480.50)		$32,837.94	

06-29-12 A11:24 OUT

Log Instructions & Notes

Originally made as: 12500 METHYLPRED. AC (PF) 80MG/ML INJECTABLE
Calculated lot number: 08102012@51 Beyond use date: 2/6/2013
FORMULA INSTRUCTIONS:

ZEBRA BAR CODES:
99600010504 - 1mL VIAL
99600020504 - 2mL VIAL
99600050504 - 5mL VIAL

pH= 5 w/ pafor Sp T= 72' Sy (8)

1071293-Lot#
Exp - Apr'17'

Date entered: 8/10/2012 2:42:54 PM Last modified: 8/10/2012 2:43:04 PM by: LAB
Checked by: ________ Date: 08/10/2012

EXHIBIT C

advancing pharmacy solutions
NECC

697 Waverly Street, Framingham, MA 01702
Tel: 800.994.6322 or 508.820.0606
Fax: 888.820.0583 or 508.820.1616
www.neccrx.com

General Overview of Policies & Procedures for Compounding Sterile Products

NECC operates in accordance with the following general guidelines when compounding sterile products:

A. Facility/Equipment

a. ISO-5 & ISO-6 Cleanroom(s).
b. Class 10 Microenvironments (barrier isolator).
c. Certified by Massachusetts Board of Pharmacy as a pharmacy with a central venous admixture service (CIVAS) in accordance with Board regulations, 247 CMR 6.01 (6)(c).

B. Monitoring & Maintenance

Comprehensive environmental monitoring program

a. All cleanroom space, air, surfaces and hoods are sampled on a weekly basis, exceeding USP 797.

C. Personnel

a. All sterile compounding is performed by properly trained and validated registered pharmacists.
b. Pharmacy personnel are trained/validated by an outside agency, Professional Compounding Centers of America (PCCA).
c. Personnel are validated on a quarterly basis.

D. Quality Assurance/Quality Control

a. USP Chemicals are obtained only from FDA registered facilities.
b. Formulations are sterilized by 0.22 micron filtration or by autoclaving.
c. Samples from final product batch lots are sent to an independent FDA registered analytical lab for sterility, endotoxin (pyrogenicity) and potency testing.
d. Tested medication is quarantined and dispensed only after the sample has tested negative for endotoxin and microbial contamination.

e. The Quality Assurance Team (QAT), made up of employees from all departments within NECC, meets regularly to review all quality related items.
f. NECC maintains strict environmental testing protocols. Results of these tests are reported via Quarterly QA Reports.
g. All sterile compounding actions are performed in compliance with NECC's Standard Operating Procedures (SOPs). These SOPs have been "mapped" against USP 797 "Pharmaceutical Compounding – sterile preparations" to ensure that all USP 797 requirements are observed.

E. Use-by Dating

Each dosage form is labeled with a BUD/expiration date appropriate to the formulation obtained from:

a. Current literature.
b. Independent stability assay.

F. Packaging

a. Compounded preparations are packaged in containers meeting USP standards.
b. Container used depends on the physical and chemical properties of the compounded preparation.

G. Dispensing

There must be a specific practitioner-patient-pharmacist relationship in place to dispense to an individual patient or facility.

H. Shipping

Medications are shipped overnight (usually via FedEx) in an appropriate container to ensure controlled temperatures and product integrity.

I. Licensing

NECC has undertaken a rigorous licensure process thus giving us the ability to legally dispense prescription medication in all 50 states.

EXHIBIT D

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Certificate Of Analysis

CLIENT: New England Compounding Center-MA

ARL #: 176896-01
LOT #: 05212012@68
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 05/22/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Methylprednisolone Acetate Specifications = 90% - 110%	80	mg/mL	83.604	104.5%	HPLC	5/23/2012

alex tang - Laboratory Supervisor

05/24/2012
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: New England Compounding Center-MA

ARL #: 176896-01
LOT #: 05212012@68
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 05/22/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	Sterile	USP 71	05/22/2012
Endotoxin	6.25 EU/mg	<0.05 EU/mg	USP 85	05/23/2012

Amar Arafat - Microbiologist — 06/05/2012 Date Reported

Sterility - 14 day sterility report. In accordance with the USP guidelines, the samples will be incubated for 14 days.

Results reported above relate only to the sample that was tested.

ARL Form QUF-078-V4 03/05/2010

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: New England Compounding Center-MA

ARL #: 176896-01
LOT #: 05212012@68
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 05/22/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility (*Preliminary*)	Sterile / Not Sterile	Sterile	USP 71	05/22/2012
Endotoxin	6.25 EU/mg	<0.05 EU/mg	USP 85	05/23/2012

Sterility - This preliminary report was issued after approximately 72 hours of incubation. In accordance with the USP guidelines, the samples will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Fungal - This preliminary report was issued after 4-5 days of incubation. In accordance with the USP guidelines, the samples will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Endotoxin - To calculate the endotoxin limit use the following formulae: EL = K/M where K = tolerance limit (EU/kg) and M = Maximum dose/kg/hour or Maximum dose/kg
Parenteral: K is 5 EU/kg for any route of administration /Intrathecal: K is 0.2 EU/kg body weight)
Radiopharmaceutical parenteral: K is 175/V or Intrathecal radiopharmaceuticals: K is 14/V, where V is the maximum recommended dose in mL.
Dermal Application: K/M, where K = 5 EU/kg and M is the (maximum dose/m2/hour × 1.80 m2)/70 Kg.

Amar Arafat - Microbiologist

05/25/2012
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Certificate Of Analysis

CLIENT: New England Compounding Center-MA

ARL #: 180509-01
LOT #: 06292012@26
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 07/03/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Methylprednisolone Acetate Specifications = 90% - 110%	80	mg/mL	81.451	101.8%	HPLC	7/5/2012

Alex Tang - Laboratory Supervisor

07/05/2012
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: New England Compounding Center-MA

ARL #: 180509-01
LOT #: 06292012@26
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 07/03/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	Sterile	USP 71	07/03/2012
Endotoxin	6.25 EU/mg	<0.05 EU/mg	USP 85	07/06/2012

Sample properties cause turbidity in growth media. Per USP 71; the sample will be inoculated into new growth media after 14 days of incubation and incubated for 4 additional days.

Amar Arafat - Microbiologist

07/17/2012
Date Reported

Sterility - 14 day sterility report. In accordance with the USP guidelines, the samples will be incubated for 14 days.

Results reported above relate only to the sample that was tested.

ARL Form QUF-078-V4 03/05/2010

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: New England Compounding Center-MA

ARL #: 180509-01
LOT #: 06292012@26
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 07/03/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility (*Preliminary*)	Sterile / Not Sterile	Sterile	USP 71	07/03/2012
Endotoxin	6.25 EU/mg	<0.05 EU/mg	USP 85	07/06/2012

Sterility - This preliminary report was issued after approximately 72 hours of incubation. In accordance with the USP guidelines, the samples will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Fungal - This preliminary report was issued after 4-5 days of incubation. In accordance with the USP guidelines, the samples will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Endotoxin - To calculate the endotoxin limit use the following formulae: EL = K/M where K = tolerance limit (EU/kg) and M = Maximum dose/kg/hour or Maximum dose/kg
Parenteral: K is 5 EU/kg for any route of administration /Intrathecal: K is 0.2 EU/kg body weight)
Radiopharmaceutical parenteral: K is 175/V or Intrathecal radiopharmaceuticals: K is 14/V, where V is the maximum recommended dose in mL.
Dermal Application: K/M, where K = 5 EU/kg and M is the (maximum dose/m2/hour × 1.80 m2)/70 Kg.

Amar Arafat - Microbiologist

07/06/2012
Date Reported

ARL Form QUF-078-V4 05/05/2010

Results reported above relate only to the sample that was tested.

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Certificate Of Analysis

CLIENT: New England Compounding Center
697 Waverly Street
Framingham, MA 01702

ARL #: 184460-01
LOT #: 08102012@51
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 08/14/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL clear vials

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Methylprednisolone Acetate Specifications = 90% - 110%	80	mg/mL	81.676	102.1%	HPLC	8/15/2012

Alex Tang - Laboratory Supervisor

08/15/2012
Date

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Certificate Of Analysis

CLIENT: New England Compounding Center
697 Waverly Street
Framingham, MA 01702

ARL #: 184460-01
LOT #: 08102012@51
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 08/14/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL clear vials

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Methylprednisolone Acetate Specifications = 90% - 110%	80	mg/mL	81.676	102.1%	HPLC	8/15/2012

Alex Tang - Laboratory Supervisor

08/15/2012
Date

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: New England Compounding Center

ARL #: 184460-01
LOT #: 08102012@51
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 08/14/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL clear vials

ANALYSIS	Limits	Results	Test Method	Date Tested
Endotoxin	6.25 EU/mg	<0.05 EU/mg	USP 85	08/16/2012

Sample properties cause turbidity in growth media. Per USP 71, the sample will be inoculated into new growth media after 14 days of incubation and incubated for 4 additional days.

Tiffany O. Hyde

Tiffany Hyde - Microbiologist

08/17/2012
Date Reported

Sterility – This preliminary report was issued after approximately 72 hours of incubation. In accordance with the USP guidelines, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Fungal – This preliminary report was issued after approximately 4 days of incubation. In accordance with the USP guidelines, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Endotoxin - To calculate the endotoxin limit use the following formulae: EL = K/M where K = tolerance limit (EU/kg) and M = Maximum dose/kg/hour or Maximum dose/kg
Parenteral: K is 5 EU/kg for any route of administration /Intrathecal: K is 0.2 EU/kg body weight)
Radiopharmaceutical parenteral: K is 175/V or Intrathecal radiopharmaceuticals: K is 14/V, where V is the maximum recommended dose in mL.
Dermal Application: K/M, where K = 5 EU/kg and M is the (maximum dose/m2/hour × 1.80 m2)/70 Kg.

Results reported above relate only to the sample that was tested.

ARL Form QUF-078-V5 08/20/2012

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: New England Compounding Center
697 Waverly Street
Framingham, MA 01702

ARL #: 184460-01
LOT #: 08102012@51
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 08/14/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL clear vials

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	No Growth at 14 Days	USP 71	08/14/2012

Sample properties cause turbidity in growth media. Per USP 71, the sample will be inoculated into new growth media after 14 days of incubation and incubated for 4 additional days.

Tiffany O. Hyde

Tiffany Hyde - Microbiologist

08/28/2012
Date Reported

Sterility – 14 day sterility report. In accordance with the USP guidelines, the sample was incubated for 14 days.

Fungal – 14 day fungal report. In accordance with the USP guidelines, the sample was incubated for 14 days.

Results reported above relate only to the sample that was tested.

ARL Form QUF-078-V5 08/20/2012

EXHIBIT E

From: Barry Cadden </O=FIRST ORGANIZATION/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BCADDEN>
Sent: Wednesday, August 10, 2011 10:37 AM
To: Glenn Chin <gchin@neccrx.com>
Subject:

What's the testing process for the large volume meds currently? I assumed that we have at least sterility testing for "all" lots of large volume injectable lots that we are dispensing but I am told that the lots for some drugs almost never coincide with the available test data. Is this true? You need to run like normal stock meds like beta repos = test every lot and just fill as you go based on the size vial + # needed or make as many lots as you like "internally" but only label vials with lot# of tested lots to cover our ass =ex.. Avastin. I was told that we are only testing rarely and dispensing many untested lots? Please clear this up + tell me what we are doing + will do. Botton line is we can't be caught with our pants at our ankles....ever.

From: Barry Cadden </O=FIRST ORGANIZATION/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BCADDEN>
Sent: Tuesday, May 22, 2012 1:50 PM
To: Glenn Chin <gchin@neccrx.com>
Subject:

This situation is exactly why Scott must be swapped into a less dangerous position! We would be fucked if this was a cardio med!!!.....

From: Barry Cadden </O=FIRST ORGANIZATION/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BCADDEN>
Sent: Tuesday, August 7, 2012 9:16 AM
To: Glenn Chin <gchin@neccrx.com>
Subject:

The "problem" CP order has my name as sign in for pump!....we need to get Scott out of that room or at least off the sign in by tomorrow. Have him be there , help, train...etc but someone else MUST sign in .....I have no idea how I am going to explain this situation but it can't continue beyong today.....see me later

thanks

From: Barry Cadden
Sent: Tuesday, July 03, 2012 2:20 PM
To: Glenn Chin
Subject:

What's going on with the materials (mops..etc) for the Uniclean, cleaning people? How are they being handled?...I ask because we have another fungal bloom on June-28th=day of last cleaning. Are the pharmacists watching these idiots or sleeping? We need to keep an eye on them + make sure that the mops..etc are not contaminated. I am getting the film again so we can check it out.....

EXHIBIT F

From:	Glenn Chin </O=FIRST ORGANIZATION/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=GCHIN>
Sent:	Monday, December 19, 2011 11:36 AM
To:	Barry Cadden <bcadden@neccrx.com>; Cory Fletcher <cfletcher@neccrx.com>
Subject:	RE: MTX

We have about 1.25KG of MTX left. It's the old Spectrum bottles. When I say old I mean OLD, it expired in 2007 according to their sticker. We make it for our injectables and we send it out for testing and it comes out pretty close. We generally under QS the lot's we make. I would probably guess that it's at about 90 to 95% potent.

From: Barry Cadden
Sent: Monday, December 19, 2011 9:32 AM
To: Glenn Chin; Gene Svirskiy; Cory Fletcher
Subject: MTX

How much MTX powder to we have in house? I am hearing that there is another backorder of commercial inj. MTX + can't find a chemical co. who has any powder in stock

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	MDL No. 2419 Dkt. No: 1:13-md-2419-RWZ
THIS DOCUMENT RELATES TO: Suits Naming the Premier Defendants	

THE PREMIER DEFENDANTS' FIRST INTERROGATORIES, REQUESTS FOR PRODUCTION OF DOCUMENTS, AND REQUESTS FOR ADMISSION PROPOUNDED TO LISA CONIGLIARO CADDEN.

Come the Defendants, Premier Orthopaedic and Sports Medicine Associates of Southern New Jersey, LLC, trading as Premier Orthopaedic Associates; Premier Orthopaedic Associates Surgical Center, LLC; Kimberly Yvette Smith, M.D., a/k/a Kimberly Yvette Smith-Martin, M.D.; Thomas Dwyer, M.D.; Richard C. DiVerniero, M.D.; and Richard Strauss, M.D. (collectively, "Premier Defendants") , pursuant to Rules 26, 33, and 34 of the Federal Rules of Civil Procedure and the Local Rules for the District of Massachusetts, and propound the following Interrogatories, Requests for Production of Documents, and Requests for Admission to Lisa Conigliaro Cadden.

Each of the following Interrogatories shall be answered under oath, in writing, separately, to the fullest possible detail, and in accordance with the definitions and instructions set forth below. The answers shall be signed by the person making them, and a copy of the answers, together with objections, if any, shall be served within thirty (30) days after the service date of these interrogatories.

You are under a duty to seasonably supplement your response with respect to any Interrogatory directly addressed to the identity and location of persons having knowledge of discoverable matters. You are under a duty to amend a prior response if you obtain information on the basis of which you know that the response was incorrect when made, or that the response, though correctly made, is no longer true, and the circumstances are such that a failure to amend the response is, in substance, a knowing concealment.

DEFINITIONS

1. As used in this document, the terms "person(s)" and "individual(s)" mean any natural individual in any capacity whatsoever or any entity or organization, including divisions, departments, and other units therein, and shall include, but not be limited to, a public or private corporation, partnership, joint venture, voluntary or unincorporated association, organization, proprietorship, trust, estate, governmental agency, commission, bureau, or department.

2. As used in this document, the term "document" means any medium upon which intelligence or information can be recorded or retrieved, and includes without limitation, the original and each copy, regardless of origin and location, of any book, pamphlet, periodical, letter, memorandum (including any memorandum or report of a meeting or conversation), invoice, bill, order form, receipt, financial statement, accounting entry, diary, calendar, telex, telegram, cable, report, record, contract, agreement, study, handwritten note, draft, working paper, chart, paper, print, laboratory record, drawing or sketch, graph, index, lists, tape, photograph, microfilm, data sheet or data processing card, or any other written, recorded, transcribed, punched, taped, filmed, or graphic matter, however produced or reproduced, which is in your possession, custody, or control, or which was, but is no longer, in your possession, custody, or control.

3. As used in this document, the terms "identification," "identify," or "identity," when used in reference to a natural individual, require you to state his or her full name and residential and business address. Use of the term "document" in connection with the Interrogatories requires you to state the number of pages and the nature of the document, its title, its date, the name or names of its authors, and recipients, and its present location and custodian.

4. "You and "your" refers to Lisa Conigliaro Cadden and each of her present and former agents, representatives, and employees, attorneys and accountants, and each person acting or purporting to act on her behalf.

5. "Communication" means any oral or written utterance, notification, or statement of any nature whatsoever, by and to whomsoever made, including, but not limited to, correspondence, conversation, dialogue, discussions, interviews, consultants, and any other understanding between or among two or more persons.

INSTRUCTIONS

1. With respect to each Interrogatory, in addition to answering the question, you are to identify all documents that support, refer to, or evidence the subject matter of each Interrogatory and your answer thereto.

   If any or all identified documents are no longer in your possession, custody, or control because of destruction, loss, or any other reason, then you must do the following with respect to each and every document:

   A. Describe the nature of the document;

   B. State the date of the document;

   C. Identify the persons who sent and received the original and the copy of the document;

   D. State in as much detail as possible the contents of the documents; and

   E. State the manner and date of disposition of the document.

   If you contend that you are entitled to withhold from production any or all documents identified herein on the basis of attorney-client privilege, the work-product doctrine, or any other ground, then do the following with respect to each and every document:

   A. Describe the nature of the document;

   B. State the date of the document;

   C. Identify the persons who sent and received the original and a copy of the document;

   D. State the subject matter of the document; and

   E. State the basis upon which you contend you are entitled to withhold the document from production.

2. All documents produced should be organized and labeled to correspond to the specific Request in response to which they are being made available or should be produced as they are kept in the usual course of business.

3. The terms "and," "or," and "and/or" should be construed either disjunctively or conjunctively so as to bring within the scope of these Interrogatories and Requests any information that might otherwise be construed as outside their scope.

4. The term "any" should be construed to include the word "all," and "all" should be construed to include "any."

5. The present tense should be construed to include the past tense, and the past tense should be construed to include the present tense.

6. The singular should be construed to include the plural, and the plural should be construed to include the singular.

7. The terms "he" and "his" should be construed to include the words "she" and "her" or "hers," respectively and vice versa.

8. "Relating to," when referring to a document shall mean mentioning, describing, connected to or with, or discussing the stated subject matter.

INTERROGATORIES

1. Describe in detail your role at NECC and Ameridose, including job title, job description, and a description of your daily duties and activities in 2011 and 2012.

ANSWER:

2. Describe in detail the steps NECC took to compound, process, stopper, seal, package, and ship methylprednisolone acetate ("MPA") in 2011 and 2012, including but not limited to:

   a) The names of the individuals performing each step;

   b) The job titles for the individuals performing each step;

   c) The specific cleanroom or location in NECC's facility where each step took place;

   d) The tools, equipment, or machinery used for each step;

   e) Any changes to NECC's methods or procedures for compounding MPA, or the location where compounding MPA took place, that occurred in 2011 or 2012.

ANSWER:

3. Identify the total amount of MPA that NECC, and separately Ameriose, produced in each quarter of 2010, 2011, and 2012.

ANSWER:

4. Identify the types of vials and closures NECC used for MPA lots numbered 05212012@68, 06292012@26, and 08102012@51 (collectively "Contaminated Lots"), including whether the vials and enclosures were prewashed or presterilized, and identify their manufacturer(s).

ANSWER:

5. Identify any and all complaints that NECC and Ameridose received related to the sterility or safety of their products, including but not limited to complaints by customers, current and former employees, and state and federal government agencies.

ANSWER:

6. Identify any customers of NECC and Ameridose who performed site visits prior to placing orders with either company.

ANSWER:

7. Describe any policies, procedures, or protocols relating to or regarding customer site visits to the NECC facility, including the areas you allowed customers to inspect.

ANSWER:

8. Identify any customers who asked for information about prior recalls of NECC and Ameridose products prior to placing orders with either company.

ANSWER:

9. Identify and describe any information you gave customers about recalled NECC and Ameridose products in 2011 and 2012.

ANSWER:

10. Identify any and all complaints NECC or Ameridose received related to their compliance with state or federal laws and regulations, including but not limited to complaints by customers, current and former employees, and state and federal government agencies.

ANSWER:

11. Identify and describe any way in which NECC's cleanrooms were modified, altered, or expanded by NECC or Ameridose.

ANSWER:

12. Identify any policies, procedures, or guidelines in place at NECC in 2012 that encouraged employees to disclose mistakes in the compounding process, even if the mistakes necessitated destruction of product or halting production.

ANSWER:

13. Describe all disciplinary or enforcement action taken against NECC or Ameridose by any state or federal government agency.

ANSWER:

VERIFICATION

STATE OF NEW JERSEY)
)
County of _____)

I, _____, after being duly sworn, hereby make oath that the foregoing answers to Interrogatories are true to the best of my knowledge, information, and belief.

_____

Sworn and subscribed before me this _____ day of _____, 2015.

_____
Notary Public

My commission expires on: _____.

REQUESTS FOR PRODUCTION

1. Produce all correspondence between you and any of the Premier Defendants, their employees, agents, or representatives.

RESPONSE:

2. Produce all correspondence and documents referring or related to the Premier Defendants' purchase of MPA from NECC in 2011 or 2012.

RESPONSE:

3. Produce all documents produced by the government to you during any civil, criminal, or administrative proceedings related to NECC's contaminated MPA.

RESPONSE:

4. Produce all policies, procedures, guidelines, instructions and training documents referring or relating to the compounding of MPA at the NECC facility.

RESPONSE:

5. Produce all documents referring or relating to NECC or Ameridose sending samples of insufficient size or volume to comply with USP 71 to ARL or any other testing laboratory.

RESPONSE:

6. Produce all documents referring or relating to any sterility, potency, endotoxin, or fungal testing that you received from ARL or any other laboratory related to MPA compounded by NECC or Ameridose in 2011 and 2012.

RESPONSE:

7. Produce all correspondence and documents referring or relating to fungal blooms or growth in or near NECC's cleanrooms.

RESPONSE:

8. Produce all documents referring or relating to complaints or communications with Liberty Industries regarding the design, manufacture, or installation of the cleanrooms at the NECC facility.

RESPONSE:

9. Produce all documents referring or relating to any complaints that NECC or Ameridose received related to the sterility or safety of their products, including but not limited to complaints by customers, current or former employees, or state or federal government agencies.

RESPONSE:

10. Produce all documents referring or relating to any complaints NECC or Ameridose received related to their compliance with state or federal laws or regulations, including but not limited to complaints by customers, current or former employees, or state or federal government agencies.

RESPONSE:

11. Produce all correspondence and documents referring or relating to NECC's response to the meningitis outbreak, including but not limited to, steps NECC took to prepare for any inspections of its facility.

RESPONSE:

12. Produce all training and instructional material for sales staff at NECC or MSM.

RESPONSE:

13. Produce copies of any and all New Jersey Pharmacy Licenses issued to NECC and/or Lisa Conigliaro Cadden, and all documents or communications between NECC and/or Lisa Conigliaro Cadden and the New Jersey Board of Pharmacy, including those referring or related to the procurement or renewal of said Licenses.

RESPONSE:

REQUESTS FOR ADMISION

1. Admit that, had any of the Premier Defendants asked for a copy of NECC's license in 2011, you would have provided a valid and up-to-date New Jersey pharmacy license.

ANSWER:

2. Admit that NECC represented to its customers, including the Premier Defendants, that it met or exceeded USP 797 standards.

ANSWER:

3. Admit that NECC represented to its customers, including the Premier Defendants, that its products, including MPA, were safe and sterile.

ANSWER:

4. Admit that the Massachusetts Board of Pharmacy ("Mass. BoP") inspected NECC on or about May 24, 2011.

ANSWER:

5. Admit that as a result of its inspection on or about May 24, 2011, the Mass. BoP issued an inspection report documenting its findings.

ANSWER:

6. Admit that NECC failed to submit a copy of the Mass. BoP's May 24, 2011 inspection report to the New Jersey Board of Pharmacy.

ANSWER:

7. Admit that NECC owed a duty to its customers to ensure that its MPA was sterile prior to distributing it.

ANSWER

Respectfully Submitted,

BLUMBERG & WOLK, LLC

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CERTIFICATE OF SERVICE

I hereby certify that on this 14th day of May, 2015, a true and accurate copy of the foregoing was served on Lisa Conigliaro Cadden by U.S. mail and on the other parties below electronically via the Court's CM/ECF system:

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